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Engagement in a Diabetes Control Program & Clinical Biomarkers in Diverse Municipality Workers

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Abstract

Engagement in a Diabetes Control Program & Clinical Biomarkers in Diverse Municipality Workers

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34.1 million adults (18 years or older) have diabetes (13.0% of US adults) according to the CDC (2020). Diabetes is complex and associated with comorbidities which requires both lifestyle changes and medication to successfully manage the condition (World Health Organization, 2016). The purpose of this dissertation is to investigate the engagement in, and impact of, a workplace diabetes control program while measuring clinical health biomarkers and healthcare utilization in a municipality. Secondary data analysis was conducted using a de-identified clinical dataset that was collected from the City of Austin (COA) Diabetes Control Program (DCP). Most participants enrolling in the COA DCP were engaged, completing three or more pharmacy visits during both 2018 (85%) & 2019 (86%). Most participants during both 2018 (64%) & 2019 (59%) had baseline HbA1c values < 7%, signifying glycemic control, with averages for 2018 & 2019 respectively (6.7 ± 1.3 & 6.9 ± 1.3). There were significant differences between 2018 & 2019 baseline values in body mass (2018: 98.1± 22.3 kg; 2019: 97.1± 21.1 kg), HbA1c (2018: 6.7± 1.3;

2019: 6.9 ± 1.3), LDL (2018: 54.4 ± 23.9 mg/dL; 2019: 49.8 ± 22.3 mg/dL), total cholesterol (2018: 146.6 ±34.2 mg/dL; 2019: 137.2± 34.9mg/dL) and triglycerides (2018: 175.9± 100.2 mg/dL; 2019: 144.7±90.6 mg/dL) ($p<0.05$). There was a trend of higher HbA1c and decreased engagement, but it was not statistically significant. Study two evaluated HbA1c change over time engaged in the COA DCP. Participants showed a significantly higher HbA1c in visit 3 in 2018 (6.95±0.l) than in visit 1 in 2018 (6.7±0.1) ($t = -4.4$, $p = 0.0002$; Participants showed a significantly higher HbA1c in visit 1 in 2019 (6.9 ± 1.3) than in visit 1 in 2018 (6.7±0.1) ($t = -3.0$, $p = 0.03$). In 2019, participants engaged in the COA DCP significantly improved HbA1c from baseline (visit 1) (6.9 ± 1.3) to visit 2 (6.7±0.1) ($t = 3.4$, $p = 0.01$). These results show a trend of HbA1c increasing during the 2018 COA DCP and HbA1c decreasing during the 2019 COA DCP. Study three evaluated cardiovascular clinical biomarkers while controlling for HbA1c and measured preventive healthcare utilization within the COA diabetic population. Three cardiovascular related clinical biomarkers (LDL, triglycerides, and total cholesterol) were significantly affected by year while controlling for HbA1c. LDL was significantly affected by year ($t = -2.6$, $p = 0.01$). Participants had a significantly higher LDL in 2018 (65.2 ± 1.1 mg/dl) compared to 2019 (60.3 ± 1.1 mg/dl) ($t = 3.3$, $p < 0.01$). Total cholesterol was significantly affected by year ($t = -4.3$, $p <0.0001$). Participants had a significantly higher total cholesterol in 2018 (146 ± 0.95 mg/dl) compared to 2019 (136 ± 0.95 mg/dl) ($t = 6.9$ $p < 0.0001$). There was a significant interaction effect of visit and year on triglycerides ($F = 4.9$, $p = 0.01$). The triglycerides in 2018 decreased by each visit but increased from visit 1 to visit 2 in 2019.

However, significant differences were only found in visit 1 between 2018 (178 ± 4.8) and 2019 (145 ± 4.8) ($t = 4.9$, $p < 0.01$). There was no significant interaction of visit and year on systolic blood pressure, HDL & Body Mass. Employees enrolled in the COA DCP completed significantly more preventive healthcare screenings than employees with diabetes not enrolled in the COA DCP. These studies help to better understand the population engaging in the COA DCP as well as evaluate clinical biomarkers in response to the COA DCP. Overall, the COA DCP population has a high percentage of participants with good glycemic control and cardiovascular clinical biomarkers within range. There should be long-term follow-up to see if these positive clinical biomarkers are maintained.

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CHAPTER I: GENERAL INTRODUCTION

34.1 million adults (18 years or older) have diabetes (13.0% of US adults) and 7.3 million adults were not aware (undiagnosed) they had diabetes according to the CDC (2020). 19.7 million adults with diabetes are within the working age range of 18-64 years old and males have a slightly higher prevalence of diabetes than women (National Diabetes Statistics Report, 2020). New cases of diabetes were higher in Hispanics and non-Hispanic blacks compared to non-Hispanic whites and non-Hispanic Asians (National Diabetes Statistics Report, 2020). The percentage of adults who knew they had blood glucose levels in the pre-diabetic range doubled, but many adults with the condition are still unaware (National Diabetes Statistics Report, 2020). Cases of type 1 and type 2 diabetes have significantly increased in United States youth, ages 10-19 years old (National Diabetes Statistics Report, 2020). Rates of diabetes is rising in the youth population, and this generation will have to live with a chronic condition longer during their life, which increases the risk of comorbidities and healthcare costs if glycemic control is not achieved long-term.

Diabetes is a major public health problem that strains the economic, physical, and mental well-being of America (Bommer et al., 2018). Excess medical costs per diabetic person increased from a 2012 estimate of $8,417 to a 2017 estimate of $9,601(National Diabetes Statistics Report, 2020). By 2030 it is expected diabetic related global costs will continue to rise (Bommer et al., 2018). Early detection and treatment can improve health outcomes and reduce the risk of complications like cardiovascular disease (O'Connell & Manson, 2019). Workplace wellness programs are an effective setting to screen for diabetes and implement lifestyle interventions to reduce the burden of diabetes (De La Torre & Goetzel, 2016).

Diabetes is a complex disease and is associated with comorbidities such as cardiovascular disease, obesity, and cognitive decline (World Health Organization, 2016). Endothelial dysfunction, which influences blood flow, may be one mechanism that is responsible for the increased risk of cardiovascular events in people with diabetes (Tabit et al., 2010). Endothelial dysfunction might also be a contributing factor to diabetes related cognitive dysfunction (Biessels & Despa, 2018). Reducing cardiovascular risk factors such as hypertension and elevated lipids may also help prevent cognitive dysfunction (Biessels & Despa, 2018). Elevated glucose levels and insulin resistance may also be contributing factors for cognitive decline associated with diabetes (Biessels & Despa, 2018).

Physical activity can reduce the risk for diabetes and comorbidities (Yang et al., 2019). Physical activity impacts metabolic health in type 2 diabetes by increasing uptake and utilization of energy, improves insulin sensitivity and may reduce BMI (Yang et al.,). Physical activity is a cost-effective intervention and widely accessible. According to the CDC, 38% of the diabetic population is considered physically inactive and 89% of the diabetic population is overweight or obese (2020). Focusing on lifestyle changes to increase physical activity in the pre-diabetic and diabetic population can help reduce the risk for comorbidities.

Physical inactivity is related to increased risk of the most prevalent chronic diseases (National Center for Health Statistics, 2017). The shift in the American workforce is creating sedentary workplaces and is a feasible target for implementation of wellness initiatives to improve health outcomes and reduce the costs of healthcare (Bureau of Labor Statistics, 2016). Implementing a comprehensive workplace wellness program should target specific lifestyle changes that will reduce the risk of chronic disease as well as disease management and include proper evaluation to show positive health outcomes (Pronk et al., 2014; Grossmeier et al., 2010). Targeted goals such as increased physical activity or weight management based on multi-component interventions are shown to be more successful in eliciting long-term health changes (Schroer et al., 2013). Most large employers are self-funded, assuming the financial burden of unhealthy employees (Kaiser Family Foundation, 2019). Offering screening and lifestyle programs to reduce the risk of chronic disease through a workplace wellness program has the potential to reduce costs and improve long-term health outcomes (Yen et al., 2010).

Many people with diabetes have comorbidities, and the screening, counseling and treatment needs exceed the time constraints of a physician visit (Kosecoff et al., 1990). Pharmacist-led medication therapy disease management (MTDM) programs have the autonomy to provide individualized diabetes education and counsel patients on lifestyle changes and medication adherence (Maeng et al., 2018). For example, a retrospective cohort study was conducted using electronic health records and insurance claims to evaluate the impact of a MTDM on healthcare utilization and cost of care (Maeng et al., 2018). The results of the study showed that patients engaged in MTDM had lower rates of inpatient admissions and lower medical costs. This model has shown to improve clinical outcomes, healthcare utilization and lower medical costs and further research should evaluate how these programs can be integrated into comprehensive workplace wellness programs.

Design and implementation of workplace wellness programs are unique to each institution. The more research can define best practices for workplace wellness programs, the more likely employers will see a positive return on investment. Support from managers and perceived social support increase participation rates (Lier et al., 2019). Establishing a wellness culture within the company is necessary to increase engagement and for the program to be successful. For example, will the employees be able to access wellness benefits during working hours or will they only be able to utilize them before or after work? When best practices are not used in the design or implementation of a workplace wellness program, outcomes such as engagement, health savings and improved health behaviors are negatively impacted (Pronk, 2014).

Where workplace wellness programs exist, policies to promote the program and allow employees time at work to participate is critical for the success of the program (Ablah et al., 2019). Employees should be given time at work to take activity breaks or flex schedules to fit in exercise (Ablah et al., 2019). Increases in physical activity at work correlate with increases in willingness to work and psychological well-being (Silva et al., 2019; Parker et al., 2019).

Measuring outcomes from workplace interventions is crucial to show benefits to both employers and employees participating in wellness programs. Wellness programs include a variety of benefits, including disease screening and management, tobacco cessation programs, health coaching, stress management programs, health education classes, and exercise classes. Evaluating wellness programs across companies is difficult because each employer offers a unique program and studies may be subjected to selection bias. Research should be conducted to determine effectiveness of the wellness program and how to adjust intervention or policies for maximum benefit (Carnethon et al., 2009).

Municipal governments are experiencing a growing rise in health care costs (Pew Charitable Trusts, 2014; Benavides & David, 2010). Rising healthcare costs are one of the primary drivers for long-term financial strain on municipalities (Sabharwal, Kiel & Hijal-Moghrabi, 2019). Wellness design and evaluation practices for municipalities face unique challenges due to city-wide office locations and diversity of professions (Morgan et al., 2011). Fewer than half the cities reporting wellness programs report formal evaluations of their programs (Morgan et al., 2011). Limited publications about successful municipal wellness programs exist and this is an area of need for future research, especially if the funds to start the program are from taxpayer dollars (Sabharwal, Kiel & Hijal-Moghrabi, 2019).

Few studies have assessed the impact of comprehensive wellness programs in municipalities over time on health outcomes and healthcare savings. Designing, implementing, and evaluating onsite wellness programs should use best practices and demonstrate positive health changes and employer savings long-term (Pronk, 2014). Wellness programs are commonly evaluated inclusively and individual components, such as physical activity or nutrition, are not evaluated for impact separately. Results from the study will impact public health by individually evaluating a MTDM program that is part of a comprehensive wellness program. The outcome of the evaluation will provide an understanding of engagement within this workplace wellness program as well as evaluating clinical biomarkers. Preventive healthcare utilization will also be understood among the diabetic population on the City of Austin insurance plan. These results will provide evidence of the engagement, impact on health outcomes and preventive healthcare utilization that can be used to improve this onsite wellness program and provide a baseline for future research within this population.

CHAPTER II: PURPOSE AND HYPOTHESIS

Study 1: To prospectively identify differences between clinical characteristics among participants actively enrolled in the 2018 & 2019 City of Austin (COA) Diabetes Control Program (DCP) model.

Hypothesis 1: There will be statistically significant differences in participants 2018 and 2019 baseline clinical measures.

Hypothesis 2: Among participants, baseline HbA1c will significantly predict engagement in the City of Austin Diabetes Control Program.

Study 2: Evaluate the effect of visit and year on HbA1c among engaged participants of the City of Austin Diabetes Control Program (Visit 1, 2, 3; Year 2018, 2019)

Hypothesis 1: There will be a statistically significant difference between HbA1c levels between 2018 and 2019.

Hypothesis 2: There will be a statistically significant decrease of HbA1c among three visits during 2019.

Study 3: To evaluate the effect of year and visit on cardiovascular variables (Total Cholesterol, LDL, Body Mass, Systolic blood pressure, HDL, Triglycerides) while controlling for HbA1c & assess preventive healthcare utilization among employees with diabetes enrolled in the City of Austin Diabetes Control Program compared to employees with diabetes not enrolled.

Hypothesis 1: There will be a statistically significant association of cardiovascular biomarkers and time in the DCP while controlling for HbA1c.

Hypothesis 2: Participants with diabetes enrolled in the 2019 COA DCP will complete significantly more preventive healthcare screenings compared to employees with diabetes not engaged in the 2019 DCP.

Research Purpose

The purpose of this dissertation is to understand engagement in a municipal workplace diabetes control program and measure clinical biomarker changes. This research will also provide an evaluation of engagement in preventive healthcare utilization in people with diabetes on the City of Austin health insurance plan. The results will guide future research and changes needed to make this program more effective and sustainable long-term.

Significance of Study

One of the gaps in workplace wellness program research is understanding engagement in medication therapy disease management (MTDM) programs within municipalities and impact on clinical outcomes (Fazel et al., 2017). The proposed study will provide significant impact to public health by understanding workplace wellness engagement and clinical biomarkers in a city-wide disease management wellness program. The benefits of a healthy working population extend beyond the workplace and can improve the overall health of our nation while reducing the economic burden of rising healthcare costs (Carnthenon et al., 2009).

Definition of Terms

- Diabetes: A chronic health condition that impacts how your body turns food into energy. Three main types of diabetes, type 1, type 2, and gestational diabetes. (HbA1c= 6.5% or higher) (CDC)
- Pre-Diabetes: Blood glucose levels higher than normal (HbA1c 5.7-6.4%) (ADA)
- Hemoglobin A1c (HbA1c): The amount of glucose (sugar) attached to hemoglobin over three months. A measure of glycemic control (CDC).
- Controlled diabetes mellitus or glycemic control: defined as HbA1c less than 7% (ADA).
- Comorbidities: the simultaneous presence of two or more diseases or medical conditions in a patient.
- Cardiovascular disease: According to the World Health Organization (WHO)- a group of disorders of heart and blood vessels that include:
    - Hypertension
    - Heart attack
    - Stroke
    - Peripheral vascular disease
    - Heart failure
- Hypertension (High Blood Pressure): systolic blood pressure of 140 mmHg or higher or diastolic blood pressure of 90 mmHg or higher, (AHA).
- Endothelial dysfunction: an impairment of the ability of the endothelium to properly maintain vascular homeostasis (Tabit et al., 2010).

- Workplace Wellness Program: "Workplace health programs are a coordinated and comprehensive set of health promotion and protection strategies implemented at the worksite that includes programs, policies, benefits, environmental supports, and links to the surrounding community designed to encourage the health and safety of all employees.", (CDC)

- Medication Therapy Disease Management Program (MTDM): distinct service or group of services provided by health care providers, including pharmacists, to ensure the best therapeutic outcomes for patients. MTDM includes five core elements: medication therapy review, a personal medication record, a medication-related action plan, intervention or referral, and documentation and follow-up. (CDC)

- Physically inactive: getting less than 10 minutes a week of moderate or vigorous activity in each physical activity category of work, leisure time and transportation (National Diabetes Statistics Report, 2020)

- Overweight: BMI of 25.0 to 29.9 kg/m^2

- Obese: BMI of 30.0 to 39.9 kg/m^2

CHAPTER III: LITERATURE REVIEW

Introduction

National Healthcare Expenditures rose to $3.5 trillion in 2017 and are expected to reach $6 trillion by 2027 (NHE-Fact-Sheet, 2019). 80% of large firms are self-funded, meaning the employer assumes the financial risk for the health claims of its employees, creating an incentive for employers to invest in wellness programs to reduce costs, improve productivity, morale, and overall health (Kaiser Family Foundation, 2019). 84% of large firms and 50% of small firms that offer health insurance benefits offer employee wellness programs (Kaiser Family Foundation, 2019). Wellness programs include a variety of benefits, including tobacco cessation programs, health coaching, stress management programs, health education classes, and exercise classes. The Affordable Care Act, passed in 2010, allows employers to offer incentives of up to 30% of the total cost of healthcare coverage, per employee plan, expanding the workplace wellness industry's revenue to $8 million (Jones, Molitor, Reif, 2018). Evaluating wellness programs across companies is difficult because each employer offers a unique program and studies may be subject to selection bias due to the observational nature of workplace wellness program evaluation. This literature review will explore workplace wellness program design, health impact and the weaknesses in measuring outcomes.

Physical inactivity is the fourth leading risk factor for death worldwide and is associated with an increased risk of metabolic syndrome, cardiovascular disease, obesity, and diabetes (National Center for Health Statistics, 2017). Overall, occupational physical activity has decreased in the United States and certain desk jobs such as software developers, accountants, and insurance sales agents report spending over 80% of their workday in a sedentary position (Bureau of Labor Statistics, 2016). A large percentage of the population spends most of their day working, making the workplace a prime place for an intervention. It is important to have the employer promote the intervention to make it successful, but also reduce the burden of healthcare costs associated with chronic diseases that can be prevented from lifestyle interventions. Measuring outcomes from workplace interventions is crucial to show benefits to both employers and employees participating in wellness programs.

Diabetes and Cardiovascular Disease

According to the American Diabetes Association, the estimated costs of diabetes in 2017 was $327 billion (“Economic Costs”, 2018). According to the CDC, over 100 million American Adults are living with prediabetes or diabetes (“New CDC Report”, 2017). Obesity and sedentary behavior are risk factors for diabetes (Toledo et al., 2007). Moderate-intensity physical activity and weight loss have been shown to prevent and improve hyperglycemia. Toledo et al., conducted a lifestyle intervention that included moderate-intensity physical activity by walking on a treadmill for 30 minutes most days and dietary counseling for 16-20 weeks (2017). Post-intervention muscle biopsies showed increased mitochondrial densities correlated with improvements in HbA1c (Toledo, 2017).

Annesi & Johnson conducted a 6-month diet and physical activity intervention to measure effects on HbA1c and discovered that change in physical activity had greater effect on HbA1c than BMI (2013).

Diabetes is complex and associated with comorbidities and requires both lifestyle changes and medication to manage the condition (World Health Organization, 2016). Self-management of diabetes is important for reducing long-term effects of this chronic disease. Self-management is defined as, "The individual's ability to manage the symptoms, treatment, physical, and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses the ability to monitor one's condition and to effect the cognitive, behavioral, and emotional responses necessary to maintain a satisfactory quality of life." (Barlow, 2001; Barlow et al., 2002).

Teaching self-management skills as well as checking on compliance with medication adherence should be incorporated into workplace wellness programs and has been shown to reduce HbA1c and reduce the risk of comorbidities (Gaede et al., 2003). Even though there is vast evidence proving the beneficial outcomes of managing diabetes through lifestyle and medication, only <10% of the adults in the US with diabetes have these risk factors controlled (Saydah , Fradkin & Cowie, 2004; Malik et al., 2007).

The American Diabetes Association Standards of Diabetes Care recommends a risk-factor based approach to decide whether statin therapy is necessary to control cardiovascular risk in people with diabetes (2018). Three variables: age, previous cardiovascular events and ADA risk factors including LDL> 100 mg/dL, hypertension, overweight or obesity and family history of premature atherosclerotic cardiovascular disease (ASCVD) are used to stratify risk ("Standards of Medical Care in Diabetes", 2018). In younger patients with no risk factors, lifestyle changes alone may be an appropriate intervention rather than statins. LDL-c is a reversible risk factor associated with cardiovascular morbidity and mortality (Bertoluci & Rocha, 2017). People with diabetes have higher cardiovascular disease (CVD) mortality and controlling LDL-c can reduce the CVD relative risk (Bertoluci & Rocha, 2017).

Lifestyle changes can lower this risk for CVD. Masana et al., evaluated lifestyle choices that can reduce the risk for CVD, including diet, alcohol consumption, tobacco use and physical activity (2017). The Mediterranean diet pattern has been shown to reduce the risk for cardiovascular disease (Masana et al., 2017).

Cardiovascular disease and physical activity share an inverse relationship and have several mediating factors, including inflammatory markers and blood pressure as major influencers. BMI and HbA1c have smaller influence but still have an impact on cardiovascular disease (Mora et al., 2007). High blood pressure effects 108 million Americans and is a risk factor for cardiovascular disease (Facts about Hypertension, 2020). Aerobic exercise reduces both systolic and diastolic blood pressure and is an integral part of lifestyle interventions (Elley, 2002).

Muchandani et al., conducted a meta-analysis to evaluate cardio-metabolic markers post-physical activity intervention and discovered significant positive changes in body weight, BMI, and waist circumference but not biomarkers such as blood pressure, blood lipids and blood glucose (Muchandani et al., 2019). Future research should include biomarkers as primary outcomes and estimate power for significant results rather than include them as secondary outcomes (Muchandani et al., 2019).

Modern Workforce

The modern workforce is aging and poses a significant concern for employers to manage chronic disease and health complications of employees. In 2000, 13% of the labor force was 55 or older and is projected to increase to 20% of the workforce by 2020 (Anderko et al., 2012). The population of workers in the United States is changing, but so is the type of work. During the 1960's almost 50% of the jobs in the United States required moderate intensity physical activity compared to less than 20% in 2008 (Church et al., 2011). The advancement of technology has created a more sedentary workforce (Church et al., 2011). Decreases in energy expenditure without compensation from calorie intake has influenced the obesity epidemic and increased the risk for chronic diseases (Goettler, Grosse, Sonntag, 2017). Overweight and obesity lead to short-term and long-term indirect costs for the employer in the form of absenteeism and presenteeism (Goettler et al., 2017). Wellness programs to target these populations in the changing U.S. workforce are still in their infancy and further research is needed to show the return on investment for the employers to reduce direct and indirect costs.

In addition to the population of the workforce that is changing, so is the distribution of the workforce. With the advancement of technology more companies are implementing teleworking, which allows employees more flexibility in terms of where they work.

Government organizations have followed behind private sector wellness programs in wellness and diversity of programs offered according to Otenyo & Smith (2017). Geography influences the type of program implemented but also the services distributed throughout a city-wide wellness program (Otenyo & Smith, 2017). For example, cities with longer sunshine days and better weather may invest in a bikeshare program to increase physical activity, but other cities that have greater access to farms and fresh produce may focus on implementing "Farm to Work" programs that increase fruit and vegetable intake (Otenyo & Smith, 2017).

Large, geographically distributed cities that include multi-site workplaces and varying professions have more challenges when implementing comprehensive workplace wellness programs (Kilpatrick et al., 2017). Kilpatrick et al., surveyed public sector employees in Australia and found that location, shift work and workload were all barriers to participate in workplace wellness. As the implementation of workplace wellness programs increase while the geographic distribution of the modern workforce expands, including more people teleworking, remote options must be available for employees that do not work at the primary site location where the program is offered.

Incentives

The Affordable Care Act approved the use of incentives to increase utilization of preventive care (Jones et al., 2018). This law allows employers to offer incentives to employees to increase engagement in wellness programs (Cuellar et al., 2017). Cuellar et al., examined the impact of preventive and health promoting behaviors when incentives were offered by 39 different employers that had the same insurance carrier (2017). The impact of financial incentives increased preventive doctor visits, lipid panel and glucose screenings compared to baseline rates by 21 to 29% but had a smaller impact on cancer screenings such as mammograms and colorectal screenings, which increased by 5.5% and 7.3% from baseline (2017).

Cuellar et al., evaluated how incentives affect subgroup populations (Cuellar et al., 2017). At baseline Hispanics and African Americans were less likely than whites to have preventive screenings and Asians were more likely than whites to have preventive screenings (Cueller et al., 2017). Incentives failed to narrow preventive service gaps among races and even widened the gap, because Asians' use of preventive services increased (Cueller et al., 2017). Future studies should measure the impact of incentives on health disparities.

Participation in wellness programs vary depending on the type of program offered and if incentives are available (Huang et al., 2016; Einav, Lee, Levin, 2018). Huang et al., conducted a study evaluating types of wellness programs offered, participation rates, and if participation rates changed when incentives were introduced (2016). Five types of wellness programs were classified as follows: "Limited"- restricted offerings including screenings and some programs, but not disease-management programs. "Comprehensive"- wide range of programs including screening, lifestyle, and disease-management programs. "Screening-focused"- wide variety of screenings but limited lifestyle or disease management programs. “Intervention-focused”- lifestyle and disease management but few screenings. “Prevention-focused”- focus on screenings for unhealthy behaviors but limited disease-management (Huang et al., 2016).

Employers that offer incentives experience a 22% higher participation compared to those employers without incentives (Huang et al., 2016). Comprehensive wellness programs have significantly higher participation regardless of incentives compared to other styles of wellness programs (Huang et al., 2016). Incentives increase the rate of participation the greatest in prevention-focused programs (Huang et al., 2016). This information is valuable when designing wellness programs because it can help target the type of services employers should offer as well as when an incentive will increase participation. Since comprehensive programs have the highest rate of participation and elicit the greatest increase from incentives, this can be used as a model for future wellness program design.

Employer Savings

Wellness programs may help employers save money in other ways besides direct change in medical costs. Providing a robust wellness program may provide a self-selection tool and attract healthy employees as well as boost retention of healthy employees (Jones et al., 2018). Jones et al., studied the types of employees that engage in wellness programs at a large university and discovered that employees with very high medical expenses and employees with very low medical expenses were less likely to engage in the wellness program (2018). Employees with higher medical expenses increased participation in wellness programs when monetary incentives were increased but increasing non-monetary incentives does not result in a higher program participation rate for this group (Jones et al., 2018).

Providing a wellness program increased the number of employees received a health screening and increased employees' belief that management cares about their wellbeing (Jones et al., 2018). This randomized controlled trial did not show savings in healthcare spending or changes in productivity, but these results were based on one year of data, and health care savings and productivity changes may not occur until multiple years later. This study elucidates non-monetary benefits of onsite wellness programs including an increase in screenings and increase in belief of employers' commitment to well-being, which may increase retention of healthy workers.

Workplace Wellness

Song and Baicker completed a cluster randomized trial to identify the effects of a multi-component workplace wellness program on economic and health outcomes in a large U.S. warehouse retail company (2019). This is one of the most recent comprehensive studies to look at the impact of workplace wellness programs on health and economic outcomes. Eight modules spanning the topics of nutrition, exercise, stress management and prevention were implemented over 18 months across 20 worksites. Outcomes measured included: self-reported health behaviors, clinical measures of health, health care spending and productivity and absenteeism (Song & Baicker, 2019). The workplace wellness program implemented consisted of mostly webinars and challenges that were incentivized with a total of $250 potential earnings across the program. The wellness program group had significantly higher rates of positive self-reported behaviors compared to the controls but there were no differences in clinical measures, health care spending, or productivity and absenteeism over an 18-month period (Song & Baicker, 2019).

This study demonstrated the ability for workplace wellness interventions to improve health behaviors but return on investment for employers and improved health outcomes may not change in the short-term. A weakness of this study is that the wellness program is evaluated as a whole, rather than individual components. Individual elements, such as physical activity or nutrition, are not evaluated for impact separately from the program. Future studies should continue to randomize treatment to reduce selection while still evaluating individual elements of a wellness program. Individual evaluation of specific programs separate from the entire wellness program will provide information about which aspects are most impactful for positive health outcomes and healthcare savings.

Evaluating workplace wellness programs is difficult because most health outcomes change longitudinally, and these measures are difficult to capture due to turnover rates of employment. Thorndike et al. conducted a randomized controlled trial to determine if a 9-month maintenance intervention following a ten-week workplace exercise and nutrition program could prevent weight regain (2012). The ten-week initial study resulted in moderate weight loss, but the 9-month internet-based maintenance intervention did not improve outcomes at the one-year follow-up (Thorndike et al., 2012). 65% of weight loss from the ten-week intervention was maintained after one year (Thorndike et al., 2012). Engagement in the online tool, provided nine months after the ten-week intervention, was low but seemed to be effective for participants that utilized this tool (Thorndike et al., 2012).

Levy & Thorndike used the same study population from the 10-week intervention and compared healthcare spending one year pre-and-post intervention (2019). Following the 10-week nutrition and exercise wellness program there were no differences in medical spending one-year post-intervention (Levy & Thorndike, 2019). This is an example of a workplace intervention working to reduce cardiovascular risk factors in the short term, but long-term health outcomes and healthcare spending are not impacted (Thorndike et al., 2012; Levy & Thorndike, 2019). The intervention was only 10-weeks long and to induce long-term changes that will result in saved healthcare expenditures the program will have to target a specific set of risk factors for a longer time. Sustainable onsite wellness programs rather than short-term interventions should be further investigated to see the association with healthcare savings.

Pharmacist-led medication therapy disease management (MTDM) is an effective intervention to improve HbA1c, systolic blood pressure, and LDL cholesterol in diabetic patients (Fazel et al., 2017). Pharmacists are integral in the interdisciplinary care team for diabetic patients within the healthcare system and wellness programs have started utilizing them within clinics to provide specialized care as part of a diabetes management program

(Maeng et al., 2018). Pharmacists in these programs have the autonomy to provide individualized diabetes education and counsel patients on lifestyle changes and medication adherence (Maeng et al., 2018). A retrospective cohort study was conducted using electronic health records and insurance claims to evaluate the impact of a MTDM on healthcare utilization and cost of care (Maeng et al., 2018). The results of the study showed that patients engaged in MTDM had lower rates of inpatient admissions and lower medical costs. This model has shown to improve clinical outcomes, healthcare utilization and lower medical costs and further research is recommended to evaluate how these programs can be integrated into comprehensive workplace wellness programs.

Engagement

Workplace wellness programs have low rates of active engagement (Mattke et al., 2013). Incentives have been shown to increase participation rates and may help to improve health behaviors in the short-term (Huang et al., 2016). Gibson et al., evaluated engagement in an online incentive-based wellness program and discovered that male employees ages 18-34 had the highest levels of engagement while male employees between 55-64 years of age had the lowest levels of engagement (2017). These employees worked for a large nondurable goods manufacturing company. The engagement for this program may have been specific to the working population and intervention design, making it difficult to have a uniform measure of engagement when evaluating different types of wellness programs in different populations.

Incentives have been shown to increase participation in wellness programs (Cuellar et al., 2017). Preferences for type of incentive to engage in different areas of wellness differs depending on socioeconomic status and demographics (Jenkins et al., 2018). Surveying the population to determine interest in incentives for specific areas of wellness may help target participation for higher risk populations (Jenkins, 2018). Understanding the interest of incentives in the population can help employers increase engagement in wellness programs targeting specific health behavior changes.

Grossmeir et al., evaluated factors that predicted employee participation, health and medical cost impact and found that incentives may not be predictive of population-level health impact although they may increase participation (2020). Organizational and leadership support was the strongest predictor of participation and impact (Grossmeir et al., 2020). Well-designed workplace wellness programs cannot impact employees positively if there isn't high participation.

Lower socioeconomic status and race are established risk factors for diabetes and cardiovascular disease (Carnethon et al., 2009). Blue collar workers typically have higher stress and less access to workplace wellness programs (Carnethon et al., 2009). Employers should aim to reduce barriers to participation for these higher risk populations by offering workplace wellness programs that are available during working hours at various worksites and allowing employees to participate without having to take paid time off (Carnethon et al., 2009).

Another barrier to participation is a concern over privacy and an employer having health-related sensitive information (Perrault, Hildenbrand & Rnoh, 2020). Communicating effectively that all health-related information will not be shared with employers or impact the employee's job is important for increasing participation among employees that may be skeptical of workplace wellness programs. Perceived health status also impacts participation. Employees that perceive themselves as healthy reported not having interest in wellness programs (Perrault, Hildenbrand & Rnoh, 2020). Offering biometric screenings to allow employees to understand their health risks can help increase participation in targeted wellness programs to influence overall health.

Engaging employees in workplace wellness programs that have the potential to improve health and can be sustainable long-term is a goal for not just employers but the overall country to reduce the economic burden of rising healthcare costs (Carnethon et al., 2009).

Outcome Measures

"Presenteeism" is defined as "employees being present at work but unable to be fully engaged in the work environment" (Lack, 2011). In the United States, presenteeism costs surpass $180 billion annually, which is greater than the $118 billion costs of absenteeism (Levin-Epstein, 2005). Presenteeism is a measurable productivity loss that is often unrecognized by employers (Schaefer, 2007).

Evidence supports that aerobic and muscle-strengthening activities significantly lower work limitations when compared to inactive employees (Walker et al., 2017). Long-term changes in physical activity had an inverse relationship with presenteeism (Walker et al., 2017). The positive findings using health assessment data suggest that investing in workplace physical activity programs will have a positive return on investment for employers by reducing employee presenteeism. For every dollar spent on wellness programs, employee medical costs fall by $3.27 and absenteeism costs fall by $2.73 (Baicker, Cutler, Song, 2010).

Traditionally employers used absenteeism as an indicator of cost related to employee health, but recently presenteeism has been shown to be a greater financial loss for employers than absenteeism (Goetzel et al., 2004). Goetzel et al., reviewed cost of health, absenteeism and presenteeism for top ten health conditions in a large medical absence database combined with productivity surveys and found 18-60% of cost to be attributed to presenteeism (2004). There is a growing body of evidence supporting well-designed and implemented wellness programs that may be able to produce a positive return on investment (Aldana, 2001; Henke et al., 2011). Evaluating presenteeism is multi-faceted and difficult to measure due to variability in scales and validity among different populations.

Improving clinical outcomes is a major goal for disease management wellness programming. Kiel & McCord conducted a retrospective evaluation of a diabetes management program and evaluated changes in Hemoglobin A1c, lipids and adherence to preventive care (2005). Mean HbA1c reduction was 1.6% and for patients with an initial uncontrolled HbA1c the reduction was 2.7% (Kiel & McCord, 2005). The mean LDL reduction was 16 mg/dL and the frequency of adherence to preventive care improved. This program was effective at improving clinical markers.

Lage & Boye determined that a 1% reduction in HbA1c resulted in a 2% reduction in all health care costs and a 13% reduction in diabetes related costs resulting in an annual cost saving of $429 and $736 (2020). Sustaining these HbA1c reductions have positive impacts on quality of life and long-term health savings (Coffey et al., 2002).

Design and Evaluation

Design and implementation of wellness programs are unique to each institution. Lier, Breuer & Dallmeyer, studied 61 companies and classified companies as white collar (43 companies) or blue collar (18 companies) to evaluate organizational factors that influence participation rates (2019). Support from managers and perceived social support impact participation rates (Lier, Breuer & Dallmeyer, 2019). Establishing a wellness culture within the company is necessary to increase engagement and for the program to be successful. When best practices are not used in the design or implementation of a workplace wellness program outcomes such as engagement, health savings and improved health behaviors are negatively impacted (Pronk, 2014).

American College of Sports Medicine (ACSM) has published a best practice guide for workplace health and wellness programs and includes nine dimensions of wellness that are needed to be successful. Leadership, as described above, is the first dimension in which organizational support and engagement are needed (Lier et al., 2019; Pronk, 2014). Relevance is the second dimension; the program needs to target the interests of the employees. Partnership between individual workers, the organization and community organizations are necessary to develop a successful wellness program. Comprehensiveness is key to seeing positive health outcomes and this element is usually missing in the literature. Programs should include health education, stress management workplace screenings, disease management and exercise (Pronk, 2014).

Implementation and engagement are needed to facilitate a successful workplace wellness program and incentives are often used to increase engagement (Pronk, 2014). Communication can be used to target subgroups and send specific messages to brand the program. Data needs to be collected and used to evaluate the program for continued program improvement and compliance needs to be considered to manage health data and safety (Pronk, 2014).

Best practice for designing wellness programs is important for effective results but best practice for evaluation of programs is critical for continued positive health outcomes and return on investment. Even workplace wellness programs that follow best practices may fail to yield a positive return on investment (ROI) one year after implementation (Grossmeier et al., 2010). Timelines for evaluation and continuous improvements based on the results are crucial for long-term workplace wellness success.

Implementation and process evaluation should be conducted during the first 12 months of programming to understand engagement in the wellness program (Grossmeier et al., 2010). Participant satisfaction, medication adherence, knowledge and motivation may be positively influenced during the first year, but it will most likely take 12-24 months to see an impact in self-esteem, life-style changes, and clinical outcomes (Grossmeier et al., 2010). Outcome evaluations are recommended to be conducted two to five years following the initiation of the workplace wellness program and include health care costs, presenteeism, absenteeism, productivity, retention and hopefully overall positive return on investment and impact on company culture (Grossmeier et al., 2010).

Return on Investment (ROI)

Comprehensive workplace wellness programs have been shown to provide a positive ROI long-term. Yen et al., evaluated the ROI of the Midwest Utility Company wellness program from 1999 to 2007 (2010). The comprehensive wellness program had 1.7 times greater savings than costs over the course of 9 years and had a statistically significant annual savings of $180 per participant. The cumulative ROI shows an increase with longer participation within the program (Yen et al., 2010). ROI was calculated using the cost of implementing the program & incentives compared to changes in medical claims, pharmacy claims and cost of time away from work (Grossmeier et al., 2010). Baseline claims costs were not significantly different between participants and non-participants

(Yen et al., 2010). This study highlights that when costs and savings of the wellness program are followed long-term, the ROI is positive.

Long-term positive ROI and impact on health outcomes in response to well-designed wellness programs has been shown in many studies, but just focusing on ROI may not capture the full benefit of the wellness program (De La Torre & Goetzel, 2016).

Value of Investment

Value of investment is a more robust measure of workplace wellness programs that may capture employee satisfaction, better talent, and higher levels of retention (De La Torre & Goetzel, 2016). Implementing workplace wellness programs can be seen as an investment for employers and fill a national void by providing screenings that can identify chronic conditions early and allow for lifestyle changes to prevent these conditions (Carnethon, 2009). To improve population health, a restructuring of focus towards preventive health and implementing wellness programs in a sustainable and scalable way is recommended (Cowart & Olson, 2019).

Value added services are sought to decrease costs and promote wellness at a population level (Cowart & Olson, 2019). Cowart & Olson define value as Value= Health Outcome/ Cost of providing care (2019). The health outcome can be measured as survival, quality of life or patient perspective. The increase in value can be measured as outcomes improving when cost of care stays the same or decreases (Cowan & Olson, 2019). Measuring health outcomes and quality of life provides a broader picture of benefits from wellness rather than just dollars saved.

Impact of COVID-19

Coronavirus disease (COVID-19), which causes acute respiratory syndrome, has changed healthcare and the world. Older adults and people with pre-existing health conditions including diabetes, hypertension & obesity are at greater risk of hospitalization and death if infected with COVID-19 (Muniyappa & Gubbi, 2020). Mortality risk was found to be significantly higher in people with diabetes infected with COVID-19 compared to patients without diabetes (Hussain et al., 2020). This highlights the need for greater prevention to reduce these conditions and different ways to reach these populations during a socially distant time.

Workplace wellness programs will have to find ways to reach populations using technology and incorporate preventive programs at a distance that are still engaging to employees. Margolis et al., conducted a cluster randomized clinical trial with patients that had uncontrolled blood pressure using home blood pressure telemonitoring and pharmacist case management (2013). The telemonitoring group had greater blood pressure control than the usual care group at 6 months and 12 months follow-up (Margolis et al., 2013). This is one example of how a wellness program can adapt using telemedicine and home monitoring and improve clinical outcomes. The COVID-19 pandemic is forcing the health and wellness industry to reevaluate how they deliver care and is highlighting the need to prevent these chronic conditions more effectively.

Summary

Unhealthy employees cause direct and indirect costs to the employer and preventive health is an important mitigator to chronic disease (Raghupathi, W., & Raghupathi, V, 2018). 90% of the $3.5 trillion of healthcare costs are related to chronic and mental health conditions (Health and Economic Costs of Chronic Disease, 2019). Cardiovascular disease is the costliest chronic condition and can be prevented through healthy lifestyle changes (Stewart, Ricci, Chee, Morganstein, 2003).

Physical inactivity is related to increased risk of the most prevalent chronic diseases (National Center for Health Statistics, 2017). The shift in the American workforce is creating sedentary workplaces and is a feasible target for implementation of wellness initiatives to improve health outcomes and reduce the costs of healthcare (Bureau of Labor Statistics, 2016). Implementing a comprehensive workplace wellness program should target specific lifestyle changes that will reduce the risk of chronic disease as well as disease management and have proper evaluation to show outcomes (Pronk et al., 2014; Grossmeier et al., 2010). Targeted goals such as increased physical activity or weight management based on multi-component interventions are shown to be more successful (Schroer, Haupt, Pieper, 2013).

Policy to promote the wellness program and allowing employees time at work to participate is critical for the success of the program (Ablah et al., 2019). Employees should be given time at work to take activity breaks or flex schedules to exercise (Ablah et al., 2019). Increases in physical activity at work correlate with increases in willingness to work and psychological well-being (Silva et al., 2019; Parker et al., 2019).

Municipal governments are experiencing a growing rise in health care costs and most cities with over 10,000 residents report the use of wellness programs (Pew Charitable Trusts, 2014; Benavides & David, 2010). Wellness design and evaluation best practices for municipalities are similar to the workplace wellness best practices reviewed above but may face unique challenges due to city-wide office locations and diversity of professions (Morgan et al., 2011). Less than half the cities reporting wellness programs report formal evaluations of their programs (Morgan et al., 2011). Limited publications about successful municipal wellness programs exist and this is an area of need for future research, especially evaluating the health and cost impact if the funds to start the program are from taxpayer dollars (Morgan et al., 2011).

Design and evaluation best practices will guide the implementation of a program that will be sustainable long-term and available year-round for participants to engage (Pronk, 2014, Grossmeier, 2010). Most of the workplace wellness interventions reviewed were implemented as online modules or classes rather than engaging activities and were offered 1-2 times per year (Jones et al., 2018; Thorndike et al., 2012; Morgan et al., 2011). Wellness champions offer social support and help guide the design and implementation of wellness programs (Wellness Champions, 2019). Wellness champions are employed volunteers that are intrinsically motivated to promote health (Wellness Champions, 2019). Wellness champion networks within the design of the workplace wellness program are essential for engagement and retention of participants (Spoonheim, Pronk, 2016; Ablah et al., 2019). Benefits of workplace wellness programs include reducing healthcare costs, retention of healthy employees, improving morale and productivity (Berry, Mirabito, Baun, 2010; Mattke et al., 2013; Mattke, Schnyer, Van Busum, 2012).

The main challenge for evaluating wellness programs is lack of definite outcome measures for success. It is suggested that future research continue to assess the impact of comprehensive wellness programs over time on health outcomes, healthcare savings and presenteeism using a variety of measurement tools to reduce error. Individual components of wellness programs should be evaluated separately for impact and return on investment. The modern workforce is changing, and healthcare costs are rising. A comprehensive wellness program should be sustainable and available across many worksites. Designing, implementing, and evaluating workplace wellness programs should use best practices and demonstrate positive health changes and employer savings long-term.

Background of the City of Austin Wellness Program

The City of Austin employs 17,120 persons and 65% of the population is male. The City of Austin is a self-insured entity and is responsible for paying the medical and pharmacy claims of the employees and dependents. Healthy Connections is the wellness program that is offered to all employees and includes 4 main components: “Know your Health Numbers”, “Get Active”, “Eat Well” and “Live Healthy”. Different components of the program are incentivized and known as “Healthy Rewards” where the employee can earn up to $150 per year for participating.

The “Know your Health Numbers” campaign involves extensive screening of the population with biometric screenings available at worksites throughout the city as well as promoting annual physical exams. This program is incentivized with 8 hours of paid leave once the employee completes their online health assessment following the screening or annual physical.

“Get Active” involves onsite and remote physical activity classes during each quarter. Participants can earn up to four hours of paid leave for attending 10 of the 12 classes in the quarter for up to two quarters throughout the year. The remote walking class requires participants to reach 50,000 steps in the week or complete 150 minutes of activity that can be tracked by an approved device or application.

“Eat Well” includes the Blue Cross Blue Shield Program Naturally Slim available to employees and dependents at no cost. In addition to this self-paced program the City of Austin provides an onsite registered dietitian available for nutritional counseling to all employees free of charge.

“Live Healthy” offers disease management programs including tobacco cessation classes and the diabetes control program (DCP), mammograms and flu shot clinics. Furthermore, there are fitness challenges and seminars offered throughout the year that the employee can participate in to earn healthy rewards.

The City of Austin Diabetes Control Program started in 2015 and has increased to over 700 participants in 2020. This is a version of a Pharmacist-led medication therapy disease management (MTDM) intervention. The City of Austin has partnered with a local pharmacy chain to provide the screenings and education to participants. Employees, dependents, and retirees with a diabetes or prediabetes diagnosis can join the program free of charge.

Participants are required to attend one visit per quarter for at least three quarters of the year to earn the incentivized coverage of medication to treat diabetes at zero cost. The incentive of diabetes medication at a $0 copay is activated after the first pharmacy visit during the year. Participants are required to attend 3 visits in a calendar year in order to stay eligible to participate in the program the following year. At each of these meetings there is a set curriculum that covers aspects of lifestyle management for diabetes that is tailored to each patient. The pharmacist also records, HbA1c, lipids, weight, and blood pressure at each visit. The curriculum covered during the 2019 pharmacy visits in the COA DCP program covers basic nutrition and physical activity benefits, preventive healthcare screenings and goal setting for long-term lifestyle changes. The primary focus for nutrition in the program is on glycemic control rather than cardiovascular disease prevention. In addition to these visits, City of Austin dependents have access to medical nutrition therapy with a certified diabetes educator or registered dietitian for zero cost.

As this program grows it is important to evaluate the clinical biomarkers and the cost-effectiveness to ensure the programming can be effective and sustainable.

CHAPTER IV: METHODS

Overview

This study was designed to measure engagement characteristics, clinical biomarkers, and healthcare utilization of a City of Austin (COA) Diabetes Control Program (DCP). Participants are City of Austin employees, dependents and retirees who voluntarily enrolled in the COA Diabetes Control Program during 2018 and 2019. Each participant functions as their own control comparing biomarkers from 2018 to 2019.

Volunteers signed the informed consent included in Appendix B. Once consent was given, participants completed the educational requirements of the program. The clinical data was stripped of all protected health information (PHI) and provided a unique identifying number by a City of Austin employee prior to the data being shared with the principal investigator.

The 2018 City of Austin Diabetes Control Program required an initial 8-hour diabetes education class followed by at least three Hemoglobin A1c (HbA1c) fingerstick measurements and cholesterol screenings in a calendar year. The 2019 City of Austin Diabetes Control Program dropped the initial 8-hour education class requirements and divided the education into four segments that are delivered by a pharmacist during visits each quarter (Appendix C). This education was tailored to the individual in response to their HbA1c result during the visit. Visit 1 includes baseline Hemoglobin A1c (HbA1c) fingerstick and cholesterol screening, an overview of diabetes, self-monitoring, and goal setting. Visit 2 includes follow-up Hemoglobin A1c (HbA1c) fingerstick and cholesterol screening, treatment options and medication overview as well as education on the impact of nutrition and physical activity on glycemic control. Visit 3 includes follow-up Hemoglobin A1c (HbA1c) fingerstick and cholesterol screening, setting physical activity goals, learning how food impacts blood glucose levels and how to read a food label. Visit 4 includes follow-up Hemoglobin A1c (HbA1c) fingerstick and cholesterol screening, reviewing previous education and assessing goals. The shift in this education delivery was in response to reducing the initial 8-hour education class, which could be a barrier to enrollment in the program due to the class only being offered during work hours. Pharmacy appointments are available during daytime, evenings, and weekends at various locations throughout the city, allowing more employees to access the program. It is of interest to understand if these changes to the design of the program impacted engagement and clinical biomarkers.

Participants

640 City of Austin employees, dependents and retirees enrolled in the City of Austin Diabetes Control Program insured by Blue Cross Blue Shield of Texas insurance. Exclusion criteria included participants with Medicare as a primary insurance policy, employees without a diagnosis of prediabetes or diabetes, and less than 18 years of age. In 2019, City of Austin reported 17,120 employees in 57 departments with 65% of the population being male. Self-reported statistics reveal 49% of the population identifies as white, 30% Hispanic or Latino and 14% black or African American.

Recruitment

Flyers for the City of Austin Diabetes Program were posted throughout City of Austin work buildings and sent digitally through promotional emails. (Appendix A). The flyer was also available at City of Austin biometric screenings and given to employees that had elevated glucose levels at the time of screening.

Data Management

A local pharmacy chain collects and retains biometric outcomes containing PHI in compliance with HIPAA standards. This data set was de-identified and provided to the PI from the COA. Data Use Agreement can be seen in Appendix D. IRB determined this study was not human subjects research (Appendix E).

Research Design

Secondary data evaluation from a prospective cohort of employees enrolled in the City of Austin Diabetes Program. This review included 640 employees enrolled in the City of Austin Diabetes Program during 2018 & 2019. A within-group study design was incorporated, with participants serving as their own controls.

CHAPTER V: STUDY #1

Engagement in a Pharmacist-led Diabetes Medication Therapy Disease Management Program.

Abstract

Background: Municipal governments are experiencing a rise in healthcare costs. Medication Therapy Disease Management (MTDM) Programs have been shown to improve clinical outcomes and healthcare costs. The objective of this study is to explore the baseline clinical characteristics and engagement of participants enrolled in the City of Austin Diabetes Control Program.

Methods: Secondary data evaluation from a prospective cohort enrolled in the City of Austin Diabetes Program. This review included 640 employees enrolled in the City of Austin Diabetes Program during 2018 & 2019. A within-group study design was incorporated, with participants serving as their own controls.

Results: Most participants enrolling in the COA DCP were engaged, completing three or more pharmacy visits during both 2018 (85%) & 2019 (86%). Most participants had baseline HbA1c values < 7% at baseline during both 2018 (64%) & 2018 (59%) with averages for 2018 & 2019 respectively (6.7 ± 1.3 & 6.9± 1.3). There were significant differences in HbA1c (2018: 6.7± 1.3; 2019: 6.9 ± 1.3), LDL (2018: 54.4 ± 23.9mg/dL; 2019: 49.8 ± 22.3 mg/dL) and triglycerides (2018: 175.9± 100.2 mg/dL; 2019: 144.7±90.6 mg/dL) between 2018 & 2019 baseline values ($p<0.05$). There was a trend of higher HbA1c and decreased engagement, but it was not statistically significant.

Conclusion: In conclusion, most of the participants who enrolled in the COA DCP were considered engaged in the program, completing three or more visits during both 2018 (85%) & 2019 (86%). 64% (2018) & 59% (2019) of the City of Austin employees enrolled in the Diabetes Control Program had baseline HbA1c levels that were considered controlled according to the American Diabetes Standard of Care, which is a higher percentage than previous reports of the general population. Understanding barriers to engagement, such has a higher HbA1c, is the first step in developing strategies to increase engagement in the targeted population.

Introduction

Health is linked to quality of life and productivity (Loeppke, 2008). Growing healthcare costs can be linked to chronic diseases driven by modifiable health risks. Reducing the burden of chronic disease can be done with engaging workplace wellness programs that foster a culture of health (Loeppke, 2008). Incentives can increase engagement and have been shown to increase savings but more importantly return a positive value on investment, which reflects the broader impact of wellness programs (Loeppke, 2008).

Diabetes is responsible for over a trillion dollars of global economic burden (Bommer et al., 2017). A 1% reduction in HbA1c has been shown to reduce all-cause total health care costs by 2% and a 13% reduction in diabetes related healthcare costs (Lage & Boye, 2020). Health coaching and monetary incentives have been shown to improve glycemic control over 5 years compared to individuals not engaging in these type of wellness programs (Raymond et al., 2019). Medication adherence has been shown to reduce healthcare costs and prevent hospital stays (Lloyd et al., 2019). Reducing barriers to engagement was a key reason for the City of Austin to shift the educational program model from 2018 to 2019.

The City of Austin implemented an onsite Diabetes Control Program in 2015 in conjunction with their healthcare provider. The program has continued to evolve and in 2020 there were 700+ participants enrolled in the program. This program is highly incentivized by covering the cost of medication and testing supplies for engaged members. In 2019, the program shifted the curriculum and requirements from 2018, which required an initial 8-hour session of education on diabetes management and a minimum of 3 HbA1c checks with a registered nurse. The current program has adopted a Pharmacist-Led Medication Management Therapy model, which partners with a local pharmacy chain to provide quarterly HbA1c & lipid checks and education about diabetes self-management.

The objective of this study is to evaluate engagement and clinical baseline values in an onsite MTDM Program. The working hypotheses are there will be statistically significant differences in participant characteristics at baseline between 2018 and 2019 and among participants, there will be statistically significant differences in engagement related to baseline HbA1c values.

At the end of the study, it is our expectation that we better understand the engagement and baseline clinical characteristics of the City of Austin Diabetes Control Program. This individual component of the greater evaluation will help to understand differences of engaged and non-engaged participants and direct future planning for increasing engagement and targeting participation in at risk populations.

Methods

Participants

640 City of Austin employees, retirees and dependents enrolled in the City of Austin Diabetes Control Program insured by Blue Cross Blue Shield insurance. Exclusion criteria includes participants with Medicare as a primary insurance policy, employees without a diagnosis of diabetes, and less than 18 years of age. In 2019, City

of Austin reported 17,120 employees in 57 departments with 65% of the population being male. Self-reported statistics reveal 49% of the population identifies as white, 30% Hispanic or Latino and 14% black or African American.

Data Collection

The City of Austin Diabetes Program partners with a local pharmacy chain to collect biomarkers of participants within the program. These datasets are shared with the City of Austin who stores the file in a secure PHI folder within their system. Deidentified datasets were provided from the City of Austin for analysis.

Statistical Analysis

Descriptive statistics were completed to understand baseline characteristics of the population. Descriptive Statistics are reported as mean ± sd. Descriptive statistics were compared using Student's t-test. Engagement was defined as participating in three or more visits and controlled diabetes mellitus was defined as HbA1c less than 7%. Logistic regression was used to analyze engagement with HbA1c as the predictor. Participants with two or fewer visits were defined as "disengaged" and coded as 0; those with three or four visits were defined as "engaged" and coded as 1. Logistic regression coefficients provide the change in the log odds of the outcome variable for a one unit increase in the predictor variable. All statistical analyses were performed in RStudio (version 1.1.456) with R Core version 3.5.

Results

Participant Characteristics

Participants' characteristics are described in Table 1. The total number of participants was 640, with each variable sample size listed for the baseline values. Pairwise deletion was used for participants who had missing data or incorrect entries. In Table 2, the descriptive statistics were completed using a listwise deletion, leading to a total sample size of 293. There were not significant differences in the baseline values between the pairwise deletion sample and listwise deletion sample. Most participants had baseline HbA1c values < 7% at baseline with averages for 2018 & 2019 respectively (6.7 ± 1.3 & 6.9 ± 1.3). There were significant differences between 2018 & 2019 baseline values in body mass (2018: 98.1± 22.3 kg; 2019: 97.1± 21.1 kg), HbA1c (2018: 6.7± 1.3; 2019: 6.9 ± 1.3), LDL (2018: 54.4 ± 23.9 mg/dL; 2019: 49.8 ± 22.3 mg/dL), total cholesterol (2018: 146.6 ±34.2 mg/dL; 2019: 137.2± 34.9mg/dL) and triglycerides (2018: 175.9± 100.2 mg/dL; 2019: 144.7±90.6 mg/dL) between groups ($p<0.05$).

Table 1. Descriptive Statistics for City of Austin Diabetes Control Program Participants

Physical Characteristics	**n**	**2018 Baseline**	**2019 Baseline**
Body Mass (kg)	421	98.1± 22.3	97.1 ± 21.1 *
BMI (kg/m^2)	419	34.2 ± 7.6	33.9 ± 7.0
HbA1c	420	6.7 ± 1.3	6.9 ± 1.3 *
LDL (mg/dL)	419	54.4 ± 23.9	49.8 ± 22.3 *
Triglycerides	417	175.9± 100.2	144.7 ± 90.6 *
Systolic BP	418	126.9 ± 17.0	127.1 ± 17.3
Diastolic BP	418	76.9± 10.8	76.6± 11.5
HDL	300	64.6± 26.5	64.2± 25.1
Total Cholesterol	418	146.6±34.2	137.2±34.9*

Note: Data are reported as mean±sd (*) *Significantly different between groups,* p < *.05 as performed with the T-Statistic*

BMI = body mass index; HbA1c = glycated hemoglobin; HDL = high-density lipoproteins LDL = low-density lipoproteins; BP= blood pressure.

Table 2. Descriptive Statistics for City of Austin Diabetes Control Program Participants

N=293

Physical Characteristics	**2018 Baseline**	**2019 Baseline**
Body Mass (kg)	97.6± 23.0	96.9 ± 21.8
BMI (kg/m^2)	34.6 ± 7.8	34.4 ± 7.3
HbA1c	6.6 ± 1.2	6.8 ± 1.2 *
LDL (mg/dL)	55.7 ± 17.9	52.2 ± 24.1 *
Triglycerides	163.0± 71.5	135.9 ± 63.7 *
Systolic BP	125.8 ± 16.7	126.7± 18.0
Diastolic BP	76.2± 11.1	76.8± 11.6
HDL	64.9± 26.6	64.4± 25.1
Total Cholesterol	152.9± 31.8	143.2± 31.1*

Note: Data are reported as mean±sd (*) *Significantly different between groups,* p < *.05 as performed with the T-Statistic. BMI = body mass index; HbA1c = glycated hemoglobin; HDL = high-density lipoproteins LDL = low-density lipoproteins; BP= blood pressure.*

Figure 1 shows the total number of participants at each visit throughout the program. The number of unique participants completing each visit can be seen in Figure 2. 2019 visit 3 had the highest number of people compared to very few people only attending visit 1 or 2 during both years. Most of the participants who enrolled were considered engaged in the program, completing three or more visits during both 2018 (85%) & 2019 (86%) (Table 3).

Figure 1. Flow of participants through the City of Austin Diabetes Control Program during 2018 & 2019

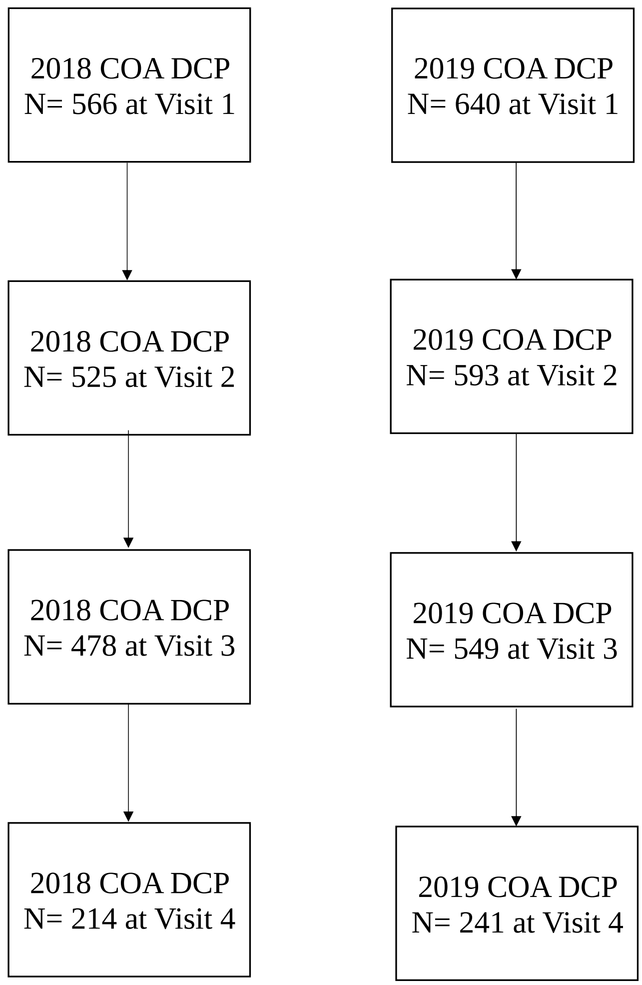
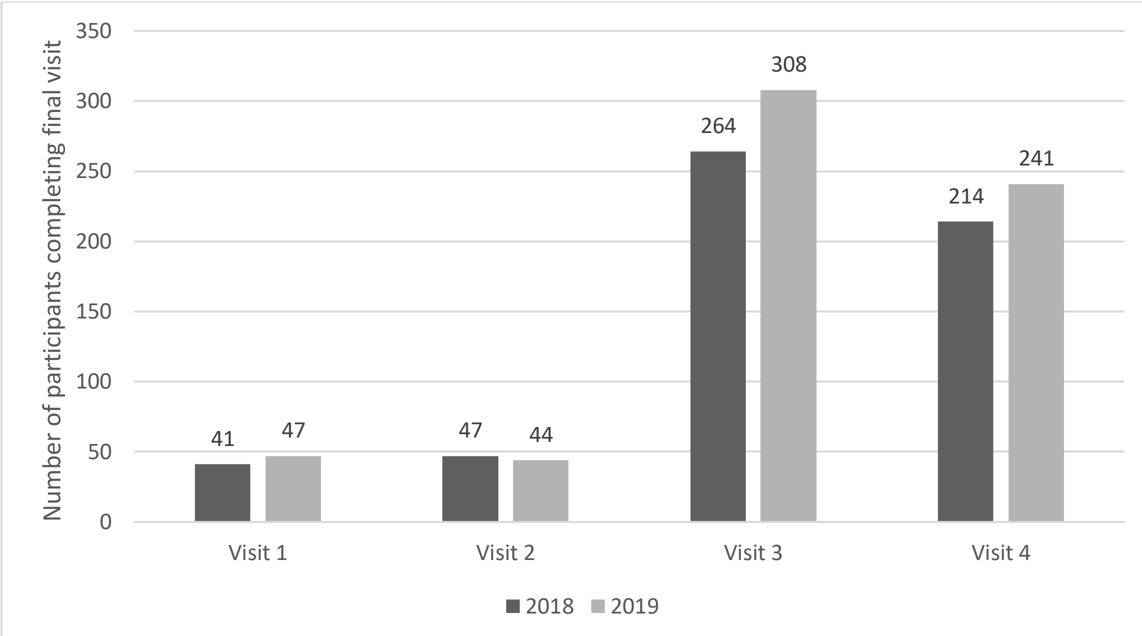


Figure 2. Number of Unique City of Austin Diabetes Control Program Participants in their Final Visit



Most participants had a controlled HbA1c at baseline during both 2018 (64%) & 2019 (59%) (Table 3).

Table 3. Glycemic Control and Engagement in City of Austin Diabetes Control Program

	2018	2019
Total number of participants	564	640
Engaged(≥3 visits)	85%	86%
HbA1c <7% at baseline	64%	59%

Table 4 describes the engagement for 2018 & 2019 participants based on glycemic control. In 2018 & 2019 more engaged participants have a controlled HbA1c at baseline. The average HbA1c for employees with controlled diabetes at baseline for 2018 was 6.0 ± 0.6 & 6.1 ± 0.6 in 2019. The average HbA1c for employees with uncontrolled diabetes at baseline was 8.1 ± 1.1 in 2018 & 2019. (Table 4).

Table 4. Descriptive Statistics by Glycemic Control in City of Austin Diabetes Control Program

Physical Characteristics	**n=**	HbA1c < 7% 2018 Baseline	HbA1c <7% 2019 Baseline	HbA1c ≥7% 2018 baseline	HbA1c ≥7% 2019 baseline
Body Mass (kg)	414	96.7 ± 21.5	96.4 ± 20.6	100.4 ± 23.5	98.2± 22.1
BMI (kg/m^2)	417	33.5 ± 7.2	33.8 ± 7.0	35.6 ± 7.6	34.1 ± 6.9
HbA1c	418	6.0 ± 0.6	6.1 ± 0.6	8.1 ± 1.1	8.1 ± 1.1
LDL (mg/dL)	242	59.0 ± 29.0	53.2 ± 15.2	57.1 ± 21.1	49.6 ± 13.7
Triglycerides	408	170.0 ± 90.8	141.9 ± 90.7	190.7 ± 115.2	151.7± 90.9
Systolic BP	412	127.6 ± 17.5	126.5 ± 17.5	125.5 ± 16.3	128.1 ± 16.9
Diastolic BP	417	76.3 ± 11.1	76.1± 11.8	76.3 ± 10.3	77.4± 11.0
HDL	295	63.9 ± 24.7	65.0 ± 23.8	66.6 ± 30.0	63.0 ± 27.4
Total Cholesterol	406	144.4 ± 30.3	137.9 ± 35.1	152.1 ± 39.8	137.0 ± 34.8

Note:

BMI = body mass index; HbA1c = glycated hemoglobin; HDL = high-density lipoproteins LDL = low-density lipoproteins; BP= blood pressure.

In 2018 & 2019, a greater percentage of participants had a baseline HbA1c ≥7% that were not engaged (< 3 visits). In 2018 & 2019, there was a higher percentage of participants that had a controlled HbA1c at baseline in people considered engaged compared to those considered not engaged (Table 5).

Table 5. Engagement by Glycemic Control in the City of Austin Diabetes Control Program

2018 DCP n=564	HbA1c < 7%	HbA1c ≥7%
Engaged (≥3 visits)	66%	34%
Not Engaged (< 3 visits)	55%	45%
2019 DCP n=640	**HbA1c< 7%**	**HbA1c ≥7%**
Engaged (≥3 visits)	60%	40%
Not Engaged (< 3 visits)	54%	46%

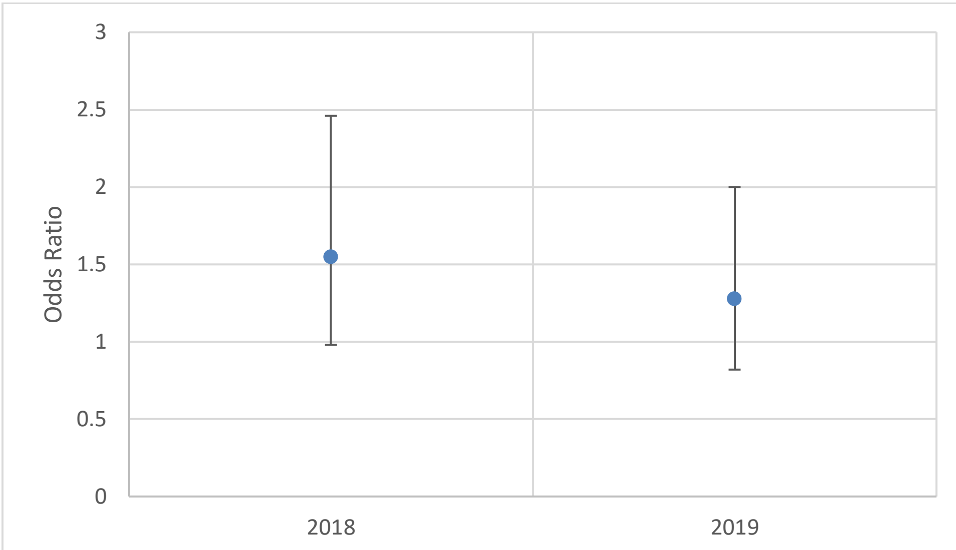
In 2018 & 2019 there were more participants with glycemic control engaged in the COA DCP compared to participants not engaged in the COA DCP (Table 6).

Table 6. Frequency Distribution of Engagement and Glycemic Control in the City of Austin Diabetes Control Program

2018 DCP n=564	HbA1c < 7%	HbA1c ≥7%
Engaged (≥3 visits)	313	164
Not Engaged (< 3 visits)	48	39
2019 DCP n=640	**HbA1c< 7%**	**HbA1c ≥7%**
Engaged (≥3 visits)	329	220
Not Engaged (< 3 visits)	49	42

Participants who had a controlled HbA1c at baseline in 2018 had 55% higher odds of being engaged in the COA DCP compared to participants that did not have a controlled HbA1c at baseline, 95% CI [0.98, 2.46]. Participants who had a controlled HbA1c at baseline in 2019 had 28% higher odds of being engaged in the COA DCP compared to participants that did not have a controlled HbA1c at baseline, 95% CI [0.82, 2.00] (Figure 2). Participants who had a controlled HbA2c had higher odds of being engaged although it did not reach statistical significance (Standards of Medical Care in Diabetes, 2019).

Figure 3. Odds Ratio of Engagement and Glycemic Control in City of Austin Diabetes Control Program



There is a trend of higher HbA1c at baseline and lower engagement in the Diabetes Control Program. For a one unit increase in HbA1c, the log odds of being engaged decreases by 0.1± 0.1. However, it did not reach statistical significance (z value = -1.9, p = 0.06). Controlled or uncontrolled HbA1(A1c <7; A1c ≥7) was not a predictor of engagement.

Discussion

This study explored the baseline clinical characteristics and engagement of participants enrolled in the City of Austin Diabetes Program. 64% (2018) & 59% (2019) of the City of Austin employees enrolled in the Diabetes Control Program had baseline HbA1c levels that were considered controlled according to the American Diabetes Standard of Care, which is higher than previous reports of the general population. Data from the National Health and Nutrition Examination Survey (NHANES) was evaluated to determine percentage of adults who meet clinical guidelines set by the American Diabetes Association (ADA) Clinical practice recommendations between 1999-2002 (Resnick et al., 2006). 50% of adults met the HbA1c target of less than 7% in this survey (Resnick et al., 2006). The City of Austin population engaging in the Diabetes Control Program have better glycemic control than the greater American population (National diabetes Statistics Report, 2020).

Among participants in the 2018 & 2019 COA DCP there were statistically significant differences between baseline measures of HbA1c, LDL and triglycerides. Participants had higher baseline LDL (2018: 54.4 ± 23.9; 2019: 49.8 ± 22.3) and triglycerides (2018: 175.9± 100.2; 2019: 144.7 ± 90.6) in 2018 compared to 2019 and lower baseline HbA1c in 2018 compared to 2019 (2018: 6.7 ± 1.3; 2019: 6.9 ± 1.3). It would be expected that participants would have better clinical measures at baseline during the 2019 program compared to the 2018 baseline measures because they had already completed a year of the COA DCP with quarterly visits to measure these values and the initial 8-hour education course provided at the beginning of the 2018 program. The quarterly visits during the 2018 year did not have the structured education that the 2019 program provided. The HbA1c baseline value increased from 2018 to 2019, meaning the 2018 COA DCP did not produce improved glycemic control following 1 year of engagement in the program.

Participants with better glycemic control at baseline also had better cardiovascular clinical values, specifically triglyceride levels, at baseline during 2018 and 2019 (Table 3). Elevated triglycerides are strongly associated with poor glycemic control (Zheng et al., 2018). Higher HbA1c at baseline trended towards lower engagement in the DCP program, but this did not reach statistical significance. People with poor glycemic control are the primary population that COA wants to engage in the program due to higher healthcare costs compared to low risk employees (Goetzel et al., 2020).

Most of the participants who enrolled in the COA DCP were considered engaged in the program, completing three or more visits during both 2018 (85%) & 2019 (86%). Few participants only attend one or two visits (Figure 1). Another disease management program offered by a large employer found that 71% of employees dropped out of the program during the first year (Lynch et al., 2006). The COA requires a minimum of three visits to earn the incentive of $0 copay for diabetes medication and supplies. This incentive may be the reason for the high percentage of engagement in the program annually. Measuring the impact of the incentive on engagement is of interest for future research. Surveying participants about medication or asking the pharmacist to include this information on the report is recommended to evaluate medication usage and change during participation in the COA DCP.

Understanding barriers to engagement, such has a higher HbA1c, is the first step in developing strategies to increase engagement in the targeted population. Future research should evaluate sociodemographic factors in addition to baseline clinical data to better understand the population engaging in the COA DCP. Increasing outreach and awareness of the COA DCP may increase participation in the DCP. Participants that have higher HbA1c at baseline may be targeted for follow-ups to try to increase engagement in the program (Ott-Holland, Shepherd, & Ryan, 2019).

CHAPTER VI: STUDY #2

Evaluating HbA1c Changes in Response to a Pharmacist Led Medication Therapy Disease Management Program (MTDM).

Abstract

<u>Background:</u> Diabetes is a major public health problem that strains the economic, physical, and mental well-being of America (Bommer et al., 2018). Early detection and treatment of diabetes can improve health outcomes. The objective of this study is to evaluate the changes in HbA1c in an employee wellness MTDM Program.

<u>Methods:</u> Secondary data evaluation from a prospective cohort enrolled in the City of Austin Diabetes Program. This review included 640 employees, retirees and dependents enrolled in the City of Austin Diabetes Program during 2018 & 2019. A within-group study design was incorporated, with participants serving as their own controls. HbA1c change over time engaged in the COA DCP was evaluated.

<u>Results:</u> Participants showed a significantly higher HbA1c in visit 3 in 2018 (6.95±0.1) than in visit 1 in 2018 (6.7±0.1) ($t = -4.4$, $p = 0.0002$; Participants showed a significantly higher HbA1c in visit 1 in 2019 (6.9±0.1) than in visit 1 in 2018 (6.7±0.1) ($t = -3.0$, $p = 0.03$). In 2019, participants engaged in the COA DCP significantly improved HbA1c from baseline (visit 1) (6.9±0.1) to visit 2 (6.7±0.1) ($t = 3.4$, $p = 0.01$).

<u>Conclusion:</u> There is a trend of HbA1c increasing during the 2018 COA DCP and HbA1c decreasing during the 2019 COA DCP. The 2018 COA DCP did not improve glycemic control. The 2019 positively impacted the glycemic control of participants. Most

participants had an HbA1c that was considered controlled at baseline, therefore, significant decreases in HbA1c during 2019, even small, implies the COA DCP is successful. Long-term follow-up to see if glycemic control is maintained is recommended.

Introduction

Currently one in three American adults have prediabetes and one in 10 have diabetes (National Diabetes Statistics Report, 2020). Diabetic complications have a significant impact on an individual's quality of life (Lloyd, Sawyer & Hopkinson, 2001). Early diagnosis and intervention to prevent these complications can have a profound impact on morbidity and mortality.

Self-insured employers are responsible for most employee's healthcare claims and can benefit from investing in workplace wellness programs to prevent and manage chronic disease (Aldana et al., 2006). Self-management skills are important in controlling blood glucose levels and implementing healthy lifestyle changes in people with diabetes. Pharmacist-Led Medication Therapy Disease Management programs have been shown to be effective at reducing HbA1c levels through teaching self-management skills and education surrounding diabetes management and lifestyle changes. (Cranor & Christensen, 2003).

Currently, there is not a standard curriculum or timeline of visits established for a MTDM program (Frederick et al., 2020). Patients who have been seeing a provider consistently for years may be able to maintain their HbA1c reductions with visits every 3-6 months (Frederick et al., 2020). Ko et al., evaluated a Pharmacist-Led Medication Management program in the Texas region and found that people with diabetes enrolled in the program had greater reductions in HbA1c compared to patients following a standard care model (2016).

The objective of this study is to evaluate the changes in HbA1c of a workplace MTDM Program. The central hypothesis is that the DCP will improve HbA1c. The working hypotheses are there will be a statistically significant difference between HbA1c levels between 2018 and 2019 and there will be a statistically significant decrease of HbA1c among three visits during 2019. Our approach to testing the working hypothesis will be to conduct a secondary data evaluation from a prospective cohort enrolled in the City of Austin Diabetes Program. The rationale for this study is that the current HbA1c change in participants is unknown. Evaluation of clinical markers in this MTDM program will help to understand if the program is effective at improving HbA1c. At the end of this study, it is our expectation that we understand the association between engagement in the City of Austin Diabetes Control Program and HbA1c control. This knowledge will help to understand the relationship between HbA1c control, and the time spent engaged in the intervention.

Methods

Secondary data analysis was conducted using a de-identified clinical dataset that was collected from the City of Austin Diabetes Program. A within- group study design was incorporated, with participants serving as their own controls.

Participants

640 City of Austin employees, retirees and dependents engaged in the Diabetes Control Program insured by Blue Cross Blue Shield insurance during 2018 & 2019. Exclusion criteria includes participants with Medicare as a primary insurance policy,

employees without a diagnosis of diabetes, and less than 18 years of age. In 2019, City of Austin reported 17,120 employees in 57 departments with 65% of the population being male. Self-reported statistics reveal 49% of the population identifies as white, 30% Hispanic or Latino and 14% black or African American.

Data Management

The City of Austin (COA) Diabetes Control Program (DCP) partners with a local pharmacy chain to collect biomarkers of participants within the program. These datasets are shared with the City of Austin wellness team who stores the file in a secure PHI folder within their system. Deidentified datasets were provided from the City of Austin for analysis.

Statistical Analysis

Descriptive statistics were completed to understand baseline characteristics of the population. Descriptive Statistics are reported as mean ± sd. Descriptive statistics were compared using Student's t-test (α= 0.05). Two-way repeated measures ANOVA was used to evaluate HbA1c change in participants engaged in the 2018 and 2019 COA DCP. Post-hoc analysis using Tukey Method was used to determine if statistical significance exists. All statistical analyses were performed in RStudio (version 1.1.456) with R Core version 3.5.1.

Results

Participant Characteristics

Participants' characteristics are described in Table 7. The total number of participants was 640, with each variable sample size listed for the baseline values. Pairwise deletion was used to remove missing data or incorrect entries. Most participants had baseline HbA1c values < 7% at baseline with averages for 2018 & 2019 respectively (6.7 ± 1.3 & 6.9 ± 1.3). There were significant differences between 2018 & 2019 baseline values in body mass (2018: 98.1± 22.3 kg; 2019: 97.1± 21.1 kg), HbA1c (2018: 6.7± 1.3; 2019: 6.9 ± 1.3), LDL (2018: 54.4 ± 23.9 mg/dL; 2019: 49.8 ± 22.3 mg/dL), total cholesterol (2018: 146.6 ±34.2 mg/dL; 2019: 137.2± 34.9mg/dL) and triglycerides (2018: 175.9± 100.2 mg/dL; 2019: 144.7±90.6 mg/dL) between groups ($p<0.05$).

Table 7. Descriptive Statistics for City of Austin Diabetes Control Program Participants

Physical Characteristics	n	2018 Baseline	2019 Baseline
Body Mass (kg)	421	98.1± 22.3	97.1 ± 21.1 *
BMI (kg/m^2)	419	34.2 ± 7.6	33.9 ± 7.0
HbA1c	420	6.7 ± 1.3	6.9 ± 1.3 *
LDL (mg/dL)	419	54.4 ± 23.9	49.8 ± 22.3 *
Triglycerides	417	175.9± 100.2	144.7 ± 90.6 *
Systolic BP	418	126.9 ± 17.0	127.1 ± 17.3
Diastolic BP	418	76.9± 10.8	76.6± 11.5
HDL	300	64.6± 26.5	64.2± 25.1
Total Cholesterol	418	146.6±34.2	137.2±34.9*

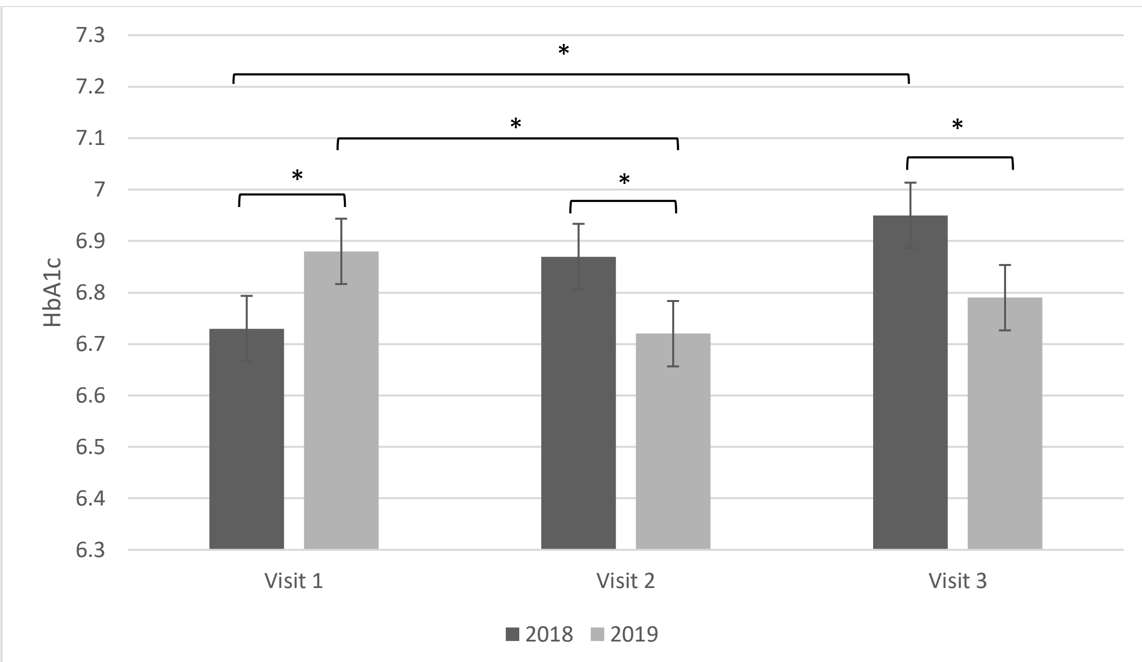
Note: Data are reported as mean±sd (*) *Significantly different between groups,* p < *.05 as performed with the T-Statistic*

BMI = body mass index; HbA1c = glycated hemoglobin; HDL = high-density lipoproteins LDL = low-density lipoproteins; BP= blood pressure.

There was a significant interaction between visit and year ($F=12.98$, $P <0.002$). Participants showed a significantly higher HbA1c in visit 1 in 2019 (6.9±0.1) than in visit 1 in 2018 (6.7±0.1) ($t = -3.0$, $p = 0.03$; Figure 3). Participants showed a significantly higher

HbA1c in visit 2 in 2018 (6.9±0.1) than in visit 2 in 2019 (6.7±0.1) ($t = 3.12$, $p = 0.02$; Figure 3). Participants showed a significantly higher HbA1c in visit 3 in 2018 (6.95±0.1) than in visit 3 in 2019 (6.8±0.1) ($t = 3.3$, $p = 0.01$; Figure 3). Participants showed a significantly higher HbA1c in visit 1 in 2019 (6.9±0.1) than in visit 2 in 2019 (6.7±0.1) ($t = 3.4$, $p = 0.01$; Figure 3). Participants showed a significantly higher HbA1c in visit 3 in 2018 (6.95±0.1) than in visit 1 in 2018 (6.7±0.1) ($t = -4.4$, $p = 0.0002$; Figure 3).

Figure 4. HbA1c Change in Engaged Participants in City of Austin Diabetes Control



Discussion

This study assessed the change in HbA1c, a measure of glucose control, over time engaged in the City of Austin Diabetes Control Program. In 2018, participants engaged in the COA DCP had an average baseline that is considered controlled (6.7 ±1.3) but there was a positive trend between visits. During the 2018 Diabetes Control Program there was not education included during the visits, rather just the initial 8-hour class before the start of the program.

In 2019, participants engaged in the COA DCP significantly improved HbA1c from baseline (visit one) to visit two (Figure 3). Although these improvements might not be clinically significant because the average baseline HbA1c was considered controlled (HbA1c < 7). The largest change in HbA1c occurred after the first visit or the initiation of the new program. During this visit the participant receives a blood glucose monitor and testing supplies as well as the initial pillar of education and the incentive for free medication is activated.

The HbA1c change from visit two to visit three during 2019 was a slight increase but not clinically significant (Figure 3). The changes seen in the COA DCP are less than a 1% reduction in HbA1c, which may not lead to initial cost savings. A 1% reduction in HbA1c leads to a 2% reduction in all health care costs and a 13% reduction in diabetes related costs (Lage & Boye, 2020). Baseline HbA1c values for both groups were both considered controlled (HbA1c<7) according to the Diabetes Standards of Care (Standards of Medical Care in Diabetes, 2019). Long-term follow-up may lead to more significant health savings and clinical improvements in the larger population (Grossmeier et al., 2010).

CHAPTER VII: STUDY #3

Evaluating Cardiovascular Biomarkers and Healthcare Utilization in Response to a Pharmacist Led Medication Therapy Disease Management Program (MTDM).

Abstract

Background: Diabetes is a major risk factor for cardiovascular disease and stroke (Malik et al., 2007). The objective of this study is to evaluate the cardiovascular clinical biomarkers and healthcare utilization of an onsite Medication Therapy Disease Management (MTDM) Program.

Methods: Secondary data evaluation from a prospective cohort enrolled in the City of Austin Diabetes Program. 640 City of Austin employees, retirees and dependents enrolled in the City of Austin Diabetes Control Program insured by Blue Cross Blue Shield insurance. A within-group study design was incorporated, with participants serving as their own controls. Cardiovascular clinical biomarkers were evaluated while controlling for HbA1c. A total sample size of 2,260 employees' preventive healthcare claims was used to evaluate healthcare utilization in City of Austin employees, retirees, and dependents with a diagnosis of diabetes.

Results: Three cardiovascular related clinical biomarkers (LDL, triglycerides, and total cholesterol) were significantly affected by year while controlling for HbA1c. LDL was significantly affected by year ($t = -2.6$, $p = 0.01$). Participants had a significantly higher LDL in 2018 (65.2 ± 1.1 mg/dl) compared to 2019 (60.3 ± 1.1 mg/dl) ($t = 3.3$, $p < 0.01$). Total cholesterol was significantly affected by year ($t = -4.3$, $p <0.0001$). Participants had a significantly higher total cholesterol in 2018 (146 ± 0.95 mg/dl) compared to 2019 (136 ± 0.95 mg/dl) ($t = 6.9$ $p < 0.0001$). There was a significant interaction effect of visit and

year on triglycerides ($F = 4.9$, $p = 0.01$). The triglycerides in 2018 decreased by each visit but increased from visit 1 to visit 2 in 2019. However, significant differences were only found in visit 1 between 2018 (178 ± 4.8 mg/dL) and 2019 (145 ± 4.8 mg/dL) ($t = 4.9$, $p < 0.01$). Employees enrolled in the COA DCP completed significantly more preventive healthcare screenings than employees with diabetes not enrolled in the COA DCP.

Conclusion: There were not significant changes in cardiovascular clinical biomarkers between visits during 2019 but there were significant changes in triglycerides, LDL, and cholesterol between 2018 and 2019. There may not have been significant changes in cardiovascular clinical biomarkers during the 2019 COA DCP in response to the diabetes control program because average baseline levels of systolic blood pressure, HDL, LDL, and total cholesterol were within normal limits. There may have been small individual improvements but not statistically significant. In 2019, employees enrolled in the COA DCP completed more preventive healthcare screenings compared to employees with diabetes not enrolled in the COA DCP. Prevention of cardiovascular disease can reduce disease burden and potentially save costs. Higher engagement in preventive services will help monitor and reduce risk factors for chronic disease.

Introduction

Diabetes is a major risk factor for cardiovascular disease and stroke (Malik et al., 2007). Managing blood glucose levels can reduce the risk for micro- and macrovascular complications among people with diabetes (Cranor & Christensen, 2003). Maintaining HbA1c at 7% or lower is an indicator of successful management of the disease ("Standards of Medical Care in Diabetes, 2019). Since diabetes is a lifelong disease, it is important to develop self-management skills to maintain blood glucose levels within the targeted range.

People with diabetes have two to four times increased risk of cardiovascular morbidity and mortality compared to people without diabetes (Bertoluci & Rocha, 2017). Recent studies show that cardiovascular risk may not be elevated in people with diabetes that don't have other risk factors for heart disease. Stratifying risk for people with diabetes based on other measures to treat accordingly can help to reduce overtreating with medication. LDL cholesterol is one of the most important CVD risk factors that can be influenced by lifestyle changes (Bertoluci & Rocha, 2017). Hypertension is another risk factor for cardiovascular disease that can be modified by lifestyle changes (Bertoluci & Rocha, 2017).

During the City of Austin Diabetes Control Program participants are educated about lifestyle changes to control HbA1c such as nutrition and exercise. Participants are also educated about annual preventive screenings and how this improves disease prevention and management. The visit curriculum can be seen in Appendix C. These lifestyle changes related to HbA1c may reduce lipids and lower blood pressure if implemented long-term, but the cardiovascular related clinical biomarkers of this intervention are currently unknown. Frederick et al., evaluated clinical biomarkers from a pharmacist-led diabetes medication management program and found no significant changes in lipids or blood pressure but did see reduction in HbA1c (2020).

Workplace wellness programs invest in preventive services to promote healthier lifestyles. There is a growing body of research evaluating preventive services value by assessing cost-savings, cost-effectiveness and estimated life-years saved (Maciosek et al., 2010). Assessing the value added from these services may be a more appropriate method to evaluate if they are a good investment. "Good value can be defined as providing substantial health benefits per dollar spent net of any savings, without necessarily saving money." (Maciosek et al., 2010). Increasing engagement in preventive screenings has been shown to increase life-years saved and costs spent on the services would be recouped (Maciosek et al., 2010).

In addition to teaching self-management skills through the COA Diabetes Control Program, participants are also reminded to complete their annual preventive screenings. Understanding healthcare utilization for preventive services among this population is of interest to see if this education increases engagement in healthcare services compared to employees with diabetes not enrolled in the City of Austin Diabetes Control Program.

The objective of this study is to evaluate the effect the COA DCP on cardiovascular variables (Total Cholesterol, LDL, Body Mass, Systolic blood pressure, HDL, Triglycerides) while controlling for HbA1c & assess preventive healthcare utilization among employees with diabetes enrolled in the City of Austin Diabetes Control Program compared to employees with diabetes not enrolled. The working hypotheses are: There will be statistically significant differences in cardiovascular biomarkers between 2018 and 2019 while controlling for HbA1c and participants with diabetes enrolled in the 2019 COA DCP will complete significantly more preventive healthcare screenings compared to employees with diabetes not engaged in the 2019 DCP.

This study is significant because it will evaluate the cardiovascular related clinical biomarkers from a MTDM program. People with diabetes are at higher risk for cardiovascular disease (Grundy et al., 1999). Modifiable cardiovascular risk factors can be influenced by lifestyle intervention to decrease the risk of cardiometabolic disease and improve quality of life (Masana et al., 2017). It is our expectation that we will understand the cardiometabolic related clinical biomarkers and preventive healthcare utilization in City of Austin employees with diabetes enrolled in the Diabetes Control Program.

Methods

Secondary data evaluation from a prospective cohort enrolled in the City of Austin Diabetes Program and healthcare utilization claims in people with a diagnosis of diabetes. A within-group study design was incorporated, with participants serving as their own controls.

Participants

640 City of Austin employees, retirees and dependents enrolled in the City of Austin Diabetes Control Program insured by Blue Cross Blue Shield insurance. Exclusion criteria includes participants with Medicare as a primary insurance policy, employees without a diagnosis of diabetes, and less than 18 years of age. In 2019, City of Austin reported 17,120 employees in 57 departments with 65% of the population being male. Self-reported statistics reveal 49% of the population identifies as white, 30% Hispanic or Latino and 14% black or African American. A total sample size of 2,260 employees' preventive

healthcare claims was used to evaluate healthcare utilization in City of Austin employees and dependents with a diagnosis of diabetes.

Data Collection

The City of Austin Diabetes Program partners with a local pharmacy to collect biomarkers of participants within the program. These datasets are shared with the City of Austin who stores the file in a secure PHI folder within their system. Deidentified datasets were provided from the City of Austin for analysis. Aggregate healthcare utilization claims for members of the insurance plan with a diagnosis of diabetes were collected from the insurance company and shared with the PI.

Statistical Analysis

Descriptive statistics were completed to understand baseline characteristics of the population. Descriptive statistics are reported as mean ± sd. Descriptive statistics were compared using Student's t-test. A total sample size of 460 was used to analyze changes in cardiovascular disease (CVD) related clinical biomarkers. CVD clinical biomarkers include body mass, systolic blood pressure, triglycerides, HDL, and LDL (Frederick et al, 2020). Linear regression was used to evaluate the effect of the number of completed visits (Visit 1, Visit 2 & Visit 3) and year (2018 & 2019) on the cardiovascular clinical biomarkers (body mass, LDL, HDL, triglycerides, systolic BP, and total cholesterol) while controlling for HbA1c.

A total sample size of 2,260 employee's preventive healthcare claims was used to evaluate healthcare utilization. Two proportion Z-tests were used to analyze the differences between annual preventive healthcare screenings between employees enrolled in the DCP and employees with diabetes that are not enrolled. Statistical significance is defined as P < 0.05. All statistical analysis was performed in RStudio (version 1.1.456) with R Core version 3.5.1.

Results

Participant Characteristics

Participants' characteristics are described in Table 8. The total number of participants was 640, with each variable sample size listed for the baseline values. Pairwise deletion was used to remove missing data or incorrect entries. Most participants had baseline HbA1c values < 7% at baseline with averages for 2018 & 2019 respectively (6.7 ± 1.3 & 6.9 ± 1.3). There were significant differences between 2018 & 2019 baseline values in body mass (2018: 98.1± 22.3 kg; 2019: 97.1± 21.1 kg), HbA1c (2018: 6.7± 1.3; 2019: 6.9 ± 1.3), LDL (2018: 54.4 ± 23.9 mg/dL; 2019: 49.8 ± 22.3 mg/dL), total cholesterol (2018: 146.6 ±34.2 mg/dL; 2019: 137.2± 34.9mg/dL) and triglycerides (2018: 175.9± 100.2 mg/dL; 2019: 144.7±90.6 mg/dL) between groups (p<0.05).

Table 8. Descriptive Statistics for City of Austin Diabetes Control Program Participants

Physical Characteristics	**n**	**2018 Baseline**	**2019 Baseline**
Body Mass (kg)	421	98.1± 22.3	97.1 ± 21.1 *
BMI (kg/m^2)	419	34.2 ± 7.6	33.9 ± 7.0
HbA1c	420	6.7 ± 1.3	6.9 ± 1.3 *
LDL (mg/dL)	419	54.4 ± 23.9	49.8 ± 22.3 *
Triglycerides	417	175.9± 100.2	144.7 ± 90.6 *
Systolic BP	418	126.9 ± 17.0	127.1 ± 17.3
Diastolic BP	418	76.9± 10.8	76.6± 11.5
HDL	300	64.6± 26.5	64.2± 25.1
Total Cholesterol	418	146.6±34.2	137.2±34.9*

Note: Data are reported as mean±sd (*) *Significantly different between groups,* p < *.05 as performed with the T-Statistic*

BMI = body mass index; HbA1c = glycated hemoglobin; HDL = high-density lipoproteins LDL = low-density lipoproteins; BP= blood pressure.

Cardiovascular Results

Three cardiovascular related clinical biomarkers (LDL, triglycerides, and total cholesterol) were significantly affected by year while controlling for HbA1c. LDL was significantly affected by year ($t = -2.6$, $p = 0.01$). Participants had a significantly higher LDL in 2018 (65.2 ± 1.1 mg/dL) compared to 2019 (60.3 ± 1.1 mg/dL) ($t = 3.28$, $p < 0.01$) with pooled data of visit and controlling for HbA1C (Figure 4). Total cholesterol was significantly affected by year ($t = -4.30$, $p < 0.0001$). Participants had a significantly higher total cholesterol in 2018 (146 ± 0.95 mg/dl) compared to 2019 (136 ± 0.95 mg/dL) ($t = 6.9$ $p < 0.0001$) with pooled data of visit and controlling for HbA1C (Figure 5). There was a significant interaction effect of visit and year on triglycerides ($F = 4.9$, $p = 0.01$) (Figure 6). The triglycerides in 2018 decreased by each visit but increased from visit 1 to visit 2 in 2019. However, significant differences were only found in the visit 1 between 2018 (178 ± 4.8 mg/dL) and 2019 (145 ± 4.8 mg/dL) ($t = 4.9$, $p < 0.01$). There was no significant interaction of visit and year on systolic blood pressure, HDL & Body Mass.

Figure 5. LDL Change in Engaged Participants in City of Austin Diabetes Control Program while Controlling for HbA1c

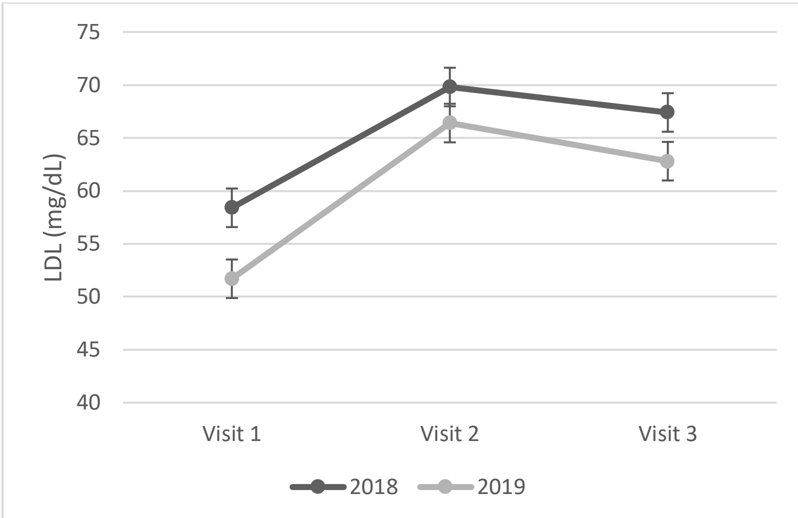


Figure 6. Total Cholesterol Change in Engaged Participants in City of Austin Diabetes Control Program while Controlling for HbA1c

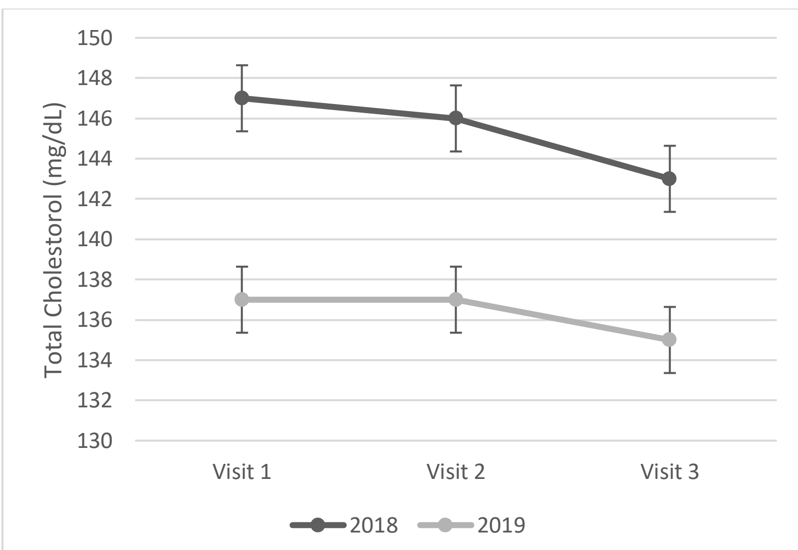
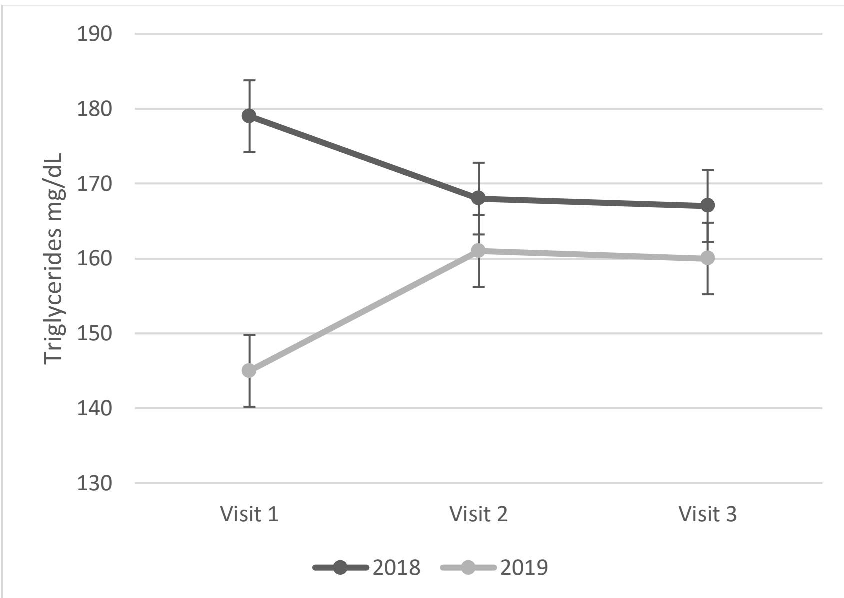


Figure 7. Triglycerides Change in Engaged Participants in City of Austin Diabetes Control Program while Controlling for HbA1c



As seen in the figures above, the cardiovascular related clinical biomarkers LDL cholesterol and total cholesterol improved between year 2018 and 2019, although both of these biomarkers were within recommended range at baseline. Triglycerides also improved between 2018 and 2019, but the baseline level for 2018 participants was not within recommended range. Small changes in these numbers are positive but not clinically significant because of the baseline number already within recommended range. Therefore, maintaining these values within recommended range is a positive outcome.

Healthcare Utilization Results

645 employees with diabetes who were enrolled in the Diabetes Control Program and 1,615 employees that have been identified as diabetic in the claims data but were not enrolled in the 2019 City of Austin Diabetes Control Program had preventive healthcare utilization claims. These claims were analyzed to understand if employees with diabetes enrolled in the COA DCP engaged in more preventive screenings during 2019 compared to employees with diabetes on the healthcare plan that were not enrolled in the COA DCP. Employees enrolled in the COA DCP completed significantly more preventive healthcare screenings than employees with diabetes that were not enrolled in the COA DCP (Table 9).

Table 9. Preventive Healthcare Utilization in City of Austin Employees with Diabetes

Preventive Screening	Percentage enrolled in DCP (n=645)	Percentage not enrolled in DCP (n= 1,615)
Annual Physicals	39.1% *	21.9%
PCP Visits	72.7% *	54.2%
Eye Exams	37.1% *	17.6%
HbA1c Screenings	67.4% *	52.1%
Creatinine Screenings	7.1% *	4.0%
Cholesterol Screenings	62.3%*	46.2%
Breast Cancer Screenings	70.0%*	30.7%
Colon Cancer Screenings	11.9%*	6.3%
Cervical Cancer Screenings	23.4%*	17.6%

(*) *Significantly different between groups,* $p < .05$ *as performed with the two proportion Z-test statistic Note: Cancer screening percentages only include members eligible for those screenings based on age and gender.*

Discussion

Triglycerides decreased significantly from visit 1 in 2018 to visit 1 in 2019. This timeframe is a year of being engaged in the 2018 program and receiving free medication for diabetes management. Triglycerides are also influenced by carbohydrate intake and with targeted education around glycemic control and nutrition, triglycerides might have improved (Odea, 1984). This may be due to better self-management and lifestyle changes. Poor glycemic control is associated with higher triglyceride levels (Zheng et al., 2018). HbA1c values at baseline were within the recommended range. The change in triglycerides may be from other positive lifestyle changes in response to the COA DCP such as exercise or changing dietary patterns.

Total cholesterol and LDL cholesterol were lower at the baseline of 2019 compared to baseline of 2018. Since these participants had already finished a year of medication management for diabetes and visits with a nurse, they may have also improved their cholesterol levels through lifestyle changes. The initial 8-hour class required at the beginning of the 2018 program has an entire section of education relating the heart healthy choices. Overall, the population engaged in the City of Austin Diabetes Control Program is already within target range for American Diabetes Association (ADA) clinical practice recommendation with their average LDL<100 mg/dL and their average total cholesterol <200 mg/dL (Standards of Medical Care in Diabetes, 2019).

Systolic blood pressure, weight, and HDL did not have any significant interaction with year or visit when controlling for HbA1c. Baseline HDL for both 2018 & 2019 is within target range with averages of 64.6 ± 25.5 mg/dL & 64.2 ± 25.1 mg/dL respectively (Standards of Medical Care in Diabetes, 2019). Systolic blood pressure is barely elevated at baseline for both 2018 & 2019 with averages being 126.9 ± 17.0 & 127.1 ± 17.3 respectively (Standards of Medical Care in Diabetes, 2019). For these cardiovascular biomarkers there may need to be targeted education to change these secondary endpoints. Since diabetes is a risk factor for cardiovascular disease and these clinical biomarkers are modifiable risk factors for cardiovascular disease, in the future, additional education about lifestyle for preventing heart disease should be included in the visits with the pharmacist. Another reason there may not be a significant interaction is because the baseline values were already within normal range for most of the cardiovascular biomarkers.

Data from the American Diabetes Association (ADA) clinical practice recommendations using the National Health and Nutrition Examination Survey (NHANES) was evaluated to determine percentage of adults who meet clinical guidelines set by the ADA between 1999-2002 (Resnick et al., 2006). Over half of adults with diabetes reported hypertension and 24% of those individuals reported cardiovascular disease (Resnick et al., 2006). Since the prevalence of hypertension and cardiovascular disease in this population is high, measuring these clinical risk factors within a diabetes management program is important.

There may not have been significant changes in cardiovascular clinical biomarkers during the 2019 COA DCP in response to the diabetes control program for two possible reasons. First, average baseline levels of systolic blood pressure, HDL, LDL and Total Cholesterol were within normal limits. There may have been small individual improvements but not statistically significant. Second, the education provided during the 2019 program curriculum was not specific to change these clinical markers, rather focused on blood glucose control through lifestyle changes like nutrition and physical activity.

Preventive health care services typically don't show immediate value and costs tend to be highest initially (Dehmer et al., 2017). Prevention of cardiovascular disease can reduce disease burden and potentially save costs and screening for lipids and blood pressure are at the top preventive services for health impact or net difference for quality adjusted life years (QALYs) (Dehmer et al., 2017). These two screenings are included in the quarterly visit for the COA DCP and may be increasing value added to employees, but clinical biomarkers are not significantly changing within one year of the program. Long-term evaluation may show positive impact on QALY or cost-effectiveness of these screenings within the COA DCP (Dehmer et al., 2017). Maeng et al., evaluated a MTDM program and showed that patients engaged had lower percentages of hospital admissions and lower medical costs. Long-term follow-up in the COA DCP may show similar results for cost savings.

Employees with diabetes enrolled in the COA DCP completed significantly more preventive healthcare screenings in every category compared to employees with diabetes on the health insurance plan that were not enrolled in the COA DCP. Preventive healthcare screenings have shown to increase life-years saved and costs spent on the services would be recouped (Maciosek et al., 2010). Preventive healthcare utilization has been shown to prevent number of deaths, with the greatest impact with preventive healthcare services that reduce the risk for cardiovascular disease (Farley et al., 2010).

Cueller et al., found that Hispanics and African Americans were less likely than whites to have preventive screenings and Asians were more likely than whites to have preventive screenings (2017). Incentives failed to narrow preventive service gaps among races. Future research should include demographic information to measure the impact of race on preventive healthcare utilization within the diabetic population.

CHAPTER VIII: DISCUSSION

These studies were conducted to determine: 1) baseline characteristics of participants enrolling in the City of Austin Diabetes Control Program and better understand engagement, 2) changes in blood glucose control among participants engaged in the City of Austin Diabetes Control Program, 3) changes in cardiovascular biomarkers among participants engaged in the City of Austin Diabetes Control Program and 4) preventive healthcare utilization among employees with diabetes on the City of Austin health insurance plan.

In study 1, 64% (2018) & 59% (2019) of the participants enrolled in the COA DCP had baseline HbA1c levels that were considered controlled, which is higher than the American population reports of 50% according to the ADA (National diabetes Statistics Report, 2020). The City of Austin Diabetes Control Program also had a high percentage of engagement during both 2018 (85%) & 2019 (86%). 54% of U.S. adults that self-identified receiving a diagnosis of diabetes reported engaging in a Diabetes Self-Management Education Program (DSME) (Adjei Boakye et al., 2018). The percentage of City of Austin Employees that have diabetes is currently unknown because this metric was not shared from the health insurance company. Measuring total cases of diabetes on the City of Austin insurance plan in future studies can help to understand the percentage of the diabetic population the program is reaching as well as inform future campaigns to increase participation.

Using data from 2011-2013 Behavioral Risk Factor Surveillance System (BRFSS), people engaging in a diabetes self-management education (DSME) were significantly more likely to be physically active, engage in at home blood glucose monitoring and conduct home foot examinations (Adjei Boakye et al., 2018). Diabetes Self-Management Education Programs are a key component to improve health biomarkers and finding ways to increase participation and engagement in these programs can have a significant impact on public health measures to mitigate long-term complications from uncontrolled diabetes (Adjei Boakye et al., 2018).

Sociodemographic characteristics of participants in the COA DCP were not collected and this is a major limitation of the current study and a direction for future research. Adjei Boayke el al., found that higher education and greater household income were associated with increased engagement in DSME (2018). Males and Hispanics were less likely to engage in DSME (Adjei Boakye et al., 2018). Evaluating these factors within the City of Austin population can help to inform future campaigns to engage populations that are less likely to participate.

In study two, participants engaged in the 2019 COA DCP significantly improved HbA1c from baseline (Figure 2). The largest decrease in HbA1c occurred after the first visit or the beginning of the new curriculum in 2019. Baseline HbA1c values in 2018 (6.7 ± 1.3) & 2019 (6.9± 1.3) were both considered controlled (HbA1c<7 %) according to the Diabetes Standards of Care (Standards of Medical Care in Diabetes, 2019). 64% in 2018 and 59% in 2019 of the total participants at baseline had HbA1c values that were considered controlled compared to only 22.3% of another Diabetes Self-Management Program of a similar size (Lorig et al., 2016). Poor glycemic control following diabetes diagnosis is associated with worse outcomes. Longer periods of HbA1c levels ≥ 8.0% were associated with increased microvascular events and mortality risk (Laiteerapong et al., 2018). HbA1c reduction is associated with a slower rise in healthcare costs over time (Bansal et al., 2018). Screening to identify pre-diabetes and diabetes as well as diabetes self-management programs are critical aspects of workplace wellness programs to prevent long-term complications of uncontrolled diabetes.

Sepah et al., evaluated long-term engagement and clinical outcomes from a digital diabetes prevention program and found that 3 years of engaging in the program participants had significantly lower HbA1c and weight compared to baseline (2017). This shows the digital delivery method was able to keep participants engaged and resulted in sustained long-term change. Long-term clinical outcomes for the COA DCP should be measured to understand if the positive changes seen during the two years measured can be sustained long-term. A digital version of the program that implements telemedicine and evaluate clinical changes to measure differences between in-person and remote options for future wellness programming may be a viable option.

In study three, the cardiovascular disease (CVD) related clinical biomarkers triglycerides, total cholesterol and LDL significantly decreased from 2018 to 2019 while controlling for HbA1c. The other CVD related clinical biomarkers HDL, blood pressure and BMI did not significantly change while controlling for HbA1c. Reducing cardiovascular disease risk through lifestyle changes is not part of the COA DCP curriculum although many features of the lifestyle changes for diabetes management overlap with reducing CVD related risk factors, such as increasing physical activity and improving nutrition. Improving carbohydrate choices, managing portions, and increasing physical activity will not only improve glycemic control but also reduce triglycerides (Newman et al., 2017).

An important clinical feature of the participants in the DCP is that some of the cardiovascular clinical biomarkers were within target recommendations at baseline (LDL<100 mg/dL, HDL>60 mg/dL) (Diabetes Standards of Care, 2019). The change seen within this group might not be significant due to the baseline values being within the recommended range, similar to the HbA1c values. Less than 50% of the adult population with Type 2 Diabetes meet the recommended clinical guidelines for the prevention of CVD (Newman et al., 2017). The average CVD related clinical risk factors in the COA DCP population are mostly within range. Comparing the average CVD clinical markers in the whole City of Austin Employee population to people engaged in the COA DCP would be of interest to see if a higher percentage of DCP participants meet these CVD clinical recommendations. Future research should include long-term follow-up to see if COA DCP participants maintain these CVD related risk factors within clinical recommendations.

These three studies together suggest that the engagement among participants enrolling in the COA DCP is high. The glucose control among engaged members is considered good with most participants exhibiting HbA1c levels within the targeted range of the clinical recommendations from the Diabetes Standards of Care (2019). Managing clinical risk factors can reduce the risk of developing complications related to diabetes years later (Lian et al., 2017). The cardiovascular related clinical biomarkers were mostly within recommended range and triglycerides, total cholesterol and LDL cholesterol significantly improved from 2018 to 2019.

The COA DCP participants also had higher percentages of preventive healthcare screenings which may contribute to good glycemic control and clinical cardiovascular risk factors within range seen in this population. Evidence suggests that for most patients with Type 2 Diabetes, a goal of maintaining a HbA1c <7% can reduce the risk for future microvascular disease risk (Newman et al., 2017). Monitoring chronic diseases are part of the best practice recommendations for municipal wellness programs but less than half of the municipalities report monitoring diabetes (Sabharwal et al., 2019). Monitoring behaviors and chronic conditions may be costly for wellness programs, but this is one area of wellness programs that have been shown to lead to better biomarkers. The City of Austin Diabetes Program monitors this chronic condition and offers education about self-management and lifestyle changes to better control diabetes. Overall, this wellness program has shown to have high engagement, great glycemic control within the engaged population, almost all cardiovascular related risk factor clinical biomarkers within recommended range and high preventive healthcare utilization.

Strengths

This research is the first to our knowledge to examine the clinical biomarkers and preventive healthcare utilization outcomes of an incentivized pharmacist-led medication therapy disease management (diabetes) program in a municipality. Municipalities face unique challenges due to the diversity of professions and dispersed worksites throughout the city (Morgan et al., 2011). This model of wellness program utilizes local pharmacy locations in addition to worksites to make the services available to all employees. The structure of the program also allows individuals longer appointments with a healthcare professional to provide education and self-management skills to control diabetes. The incentive structure of the program provides free medication, which removes the barrier of cost that is commonly associated with noncompliance of medication in diabetes. Overall, this subgroup population has shown to have very good glycemic control and cardiovascular risk factors within target range.

Bias

There are a few areas of potential bias with the present study. The pharmacist-led visits were provided free of charge to patients and funded through the health plan at the workplace (like a "closed" network). This program is also incentivized by providing medication free of charge to participants that meet the requirements.

The enrollment in the program is voluntary. The program is also highly incentivized which can skew engagement to people that need the benefit. Evaluating workplace wellness programs is necessary and this type of design can lead to potential bias. There was not data available to compare another diabetes program or a similar program in a different population. We have designed this study to use participants to serve as their own control.

Limitations

The results of the current dissertation will be limited to City of Austin employees, dependents and retirees enrolled in the Diabetes Control Program that live in the southern United States. However, the results will elucidate the effectiveness to improve clinical biomarkers in response to this model of workplace wellness program within the COA population, which is invaluable information.

Demographic, age, and sex information was not collected as part of the City of Austin Diabetes Program. This missing data limits the ability to stratify analysis to understand differences in demographics, age, and sex. The percentage of male and self-identified demographics of the City of Austin Employee population has been provided. A systematic review was conducted to evaluate if diabetes self-management education improved glycemic control in Hispanic patients and the outcomes showed a -0.25% reduction in HbA1c post-intervention (Ferguson, Swan & Smaldone, 2015). This reduction within HbA1c is greater than the reduction seen within the 2019 COA DCP (-0.09).

Another limitation to this study is the results do not differentiate between type 1 and type 2 diabetes. Type 2 diabetes accounts for 90-95% of all diabetes cases according to the CDC (National diabetes Statistics Report, 2020). Therefore, the results from this study are most likely to be representative of type 2 diabetes. Medications prescribed to manage glucose control were not included in the data recorded. Future studies should include prescriptions and dosing to better understand the cost of the program and be able to calculate return on investment. This study can be the framework for future research in workplace wellness within municipalities.

Future Research

The City of Austin Diabetes Control program has a high percentage of employees with a HbA1c <7% and a large percentage of participants that enroll in the program stay engaged by completing three or more visits in a calendar year (85% in 2018 & 86% in 2019). Understanding the trends of glucose control within all employees with diabetes on the City of Austin insurance plan would be of interest to measure how HbA1c varies between participants enrolled in the COA DCP compared to those that are not. Working with the insurance carrier to obtain these aggregate trends in HbA1c for the whole population while protecting individual privacy would be impactful for future evaluation.

Stratifying the Diabetes Control Program by glycemic control in the future is of interest. For example, participants that have a controlled HbA1c <7% at baseline would complete two visits during the calendar year (one visit every 6 months) and participants that had an uncontrolled HbA1c ≥7% would complete the 3+ visits to be considered engaged (the current model). If participants that have glycemic control at baseline are able to maintain glycemic control with less visits, this is a cost-saving attribute for the City of Austin. Tailoring the intervention to the population needs is important, and future research is needed to understand what the best intervention timeline is for optimal glycemic control and cost savings.

In the future, it is recommended that in addition to the clinical data collected during the visits, the initial visit will also include collection of demographic information, including age, sex, and ethnicity. Missing this demographic information was a limitation because without it, measuring engagement characteristics was difficult. It is important to understand the differences in the population demographics of those staying engaged in the program compared to those that do not complete the program. Studying trends in engagement can help future promotion of the program to target high risk populations that may not be enrolling or staying engaged.

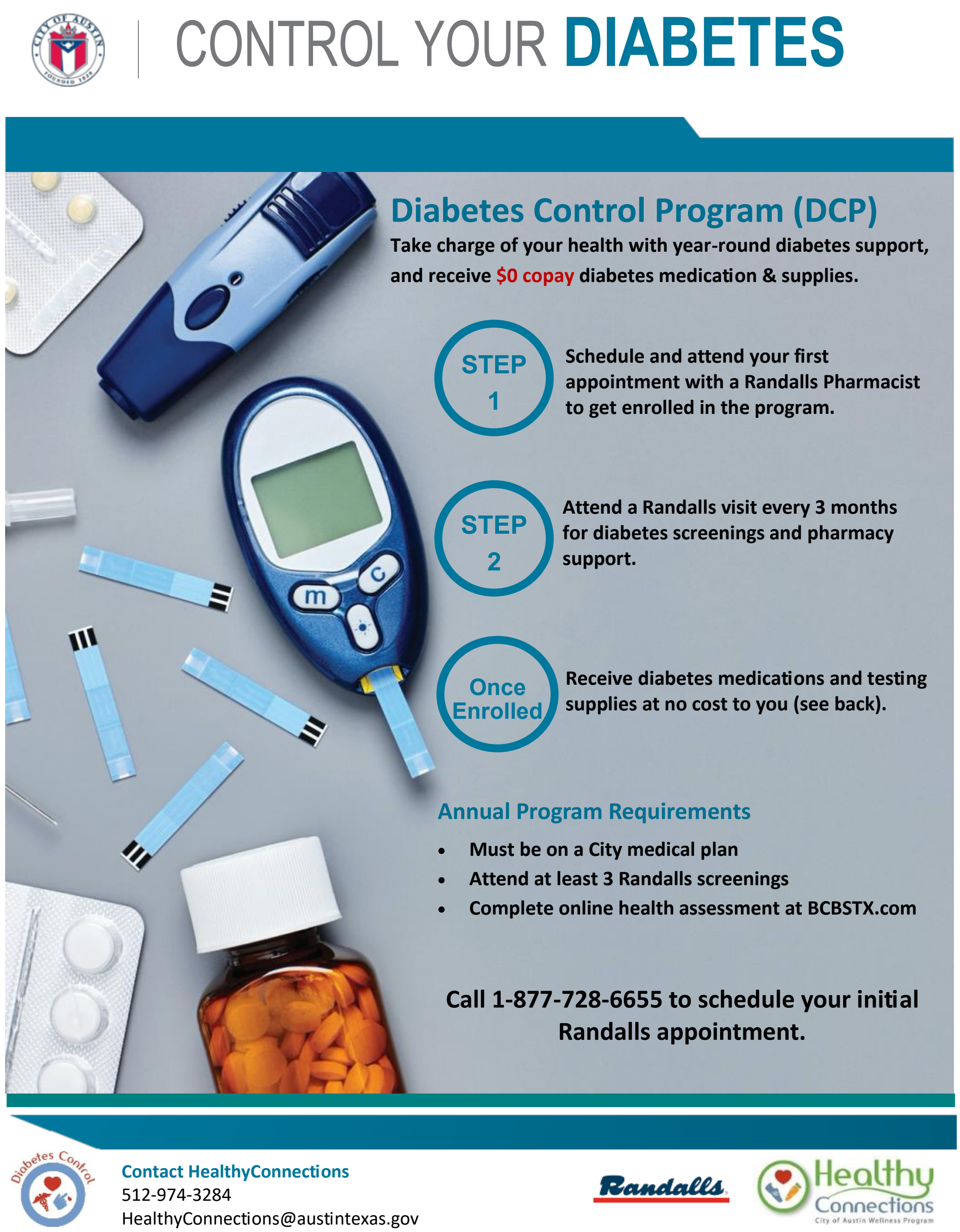
Adapting wellness interventions to be available during teleworking is more important than ever following the COVID-19 Pandemic. The ability to reach employees outside of the traditional workplace is the future of wellness and utilizing telemedicine can be effective at improving clinical outcomes (Margolis et al., 2013). Measuring changes between 2019 and 2020 during the COVID-19 Pandemic is an important next step to understand how engagement changed during this time. This information can help guide future planning to allow this program to adapt to reach participants remotely through telemedicine.

Evaluating the educational component delivered during the pharmacy visits for increased knowledge and increased self-efficacy regarding diabetes disease management is important in future studies. Huang et al., reported self-efficacy of medication use being positively associated with diabetes medication adherence which leads to better HbA1c control (2018). The structure of the City of Austin Diabetes Control program allows participants to have access to individual diabetes education and medication management while monitoring changes in HbA1c and lipids quarterly. The time spent at a pharmacy visit during this program discussing personal labs, medications and health behaviors is much longer than a typical appointment with a general physician (Kosecoff et al., 1990). The diabetes empowerment scale is a tool developed to measure diabetes related psychosocial self-efficacy (Anderson et al., 2000). This tool can be added to the baseline data and annual follow-up to measure changes in diabetes related self-efficacy in response to the COA DCP.

Overall, the City of Austin Diabetes Control Program evaluation shows that clinical markers related to diabetes management and cardiovascular disease are within recommended ranges for most of the population, according to the Diabetes Standards of Care. Future research should understand the influence of sociodemographic factors and long-term impact on clinical markers. The educational component included in the COA DCP should be evaluated and determining the cost effectiveness of this program long-term is of interest.

APPENDICES

Appendix A: Recruitment flyer



Appendix B: Diabetes Control Program Consent Form

Diabetes Control Program Recruitment Flyer

CONSENT TO PARATICIPATE AND RELEASE MEDICAL INFORMATION

I am voluntarily participating in The City of Austin Diabetes Control Program (DCP). My participation will require that my pharmacist obtain and share certain medical/health information about my condition from my physician and/or other members of my health care team including City of Austin employee benefits staff. By signing this form, I am giving my authorization for my medication information to be shared with my pharmacist, my physician(s) office, the DCP coordinator, City of Austin Employee Benefits Division or health care providers participating in my care, to be used specifically and confidentially for my care, to assess quality of care and to administer the program. Further, I give my authorization that data appropriately de-identified to protect my identity and condition may be aggregated with similarly blinded data from other patients enrolled in the same program for research and educational proposes. “De-identified” data means health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual in accordance with the Health Insurance Portability and Accountability Act.

I understand that I may revoke this authorization at any time by giving written notice to The City of Austin. In such case, I understand and agree that actions taken by any party related to the DCP program that relied upon my prior consent would stand. Also, I understand that if this consent is not revoked, it will continue for the time period that I am enrolled in the program and will expire automatically should I discontinue my participation in DCP program.

I understand that I am required to sign this authorization as a condition of my participation in the Diabetes Control Program.

I understand that the information disclosed by this authorization may be subject to re-disclosure by the recipients listed above and, in that case, will no longer be protected by the Health Insurance Portability and Accountability Act Privacy Rule [45 CFR Part 164], and the Privacy Act of 1974 [5 USC 552a].

Participant Signature: ______________________________ Date: ____________

PLEASE PRINT

First Name: _________________________ Last Name: _________________________

Employee ID Number (if applies): _________________

Date of Birth: ______________________ Last 4 of SSN: ☐ ☐ ☐ ☐

Email address**:** _______________________________________

Circle: Employee Retiree Spouse/Dependent

Appendix C: Curriculum by Visit in 2019 COA DCP

Appendix D: Data Use Agreement

DATA USE AGREEMENT
UTA 11-___
This Data Use Agreement (the "DUA") is entered into between the Parties identified below. In consideration of the mutual covenants and premises contained herein, the parties hereby agree as follows:

The Terms and Conditions for Data Use Agreement attached hereto as Exhibit A are incorporated herein by reference in their entirety (the "Terms and Conditions"). Capitalized terms used in this DUA without definition shall have the meanings given to them in the Terms and Conditions. In addition to the signatures of each Party identified in Section 1, signature is also required from the Contact Person for The University of Texas at Austin.

1. Parties (name, address for notice)	
The University of Texas at Austin ("University") Attn: [John Batholomew] Addr: 2109 San Jacinto Blvd, Austin, TX 78712 Phone: 512 232 602 [information for UT College responsible for LDS exchange]	[City of Austin Healthy Connections] Attn: Chris Vykukal Addr: 505 Barton Springs Rd. Austin, TX 78704 Phone: 512-585-7811
2. Party's Contact Person (name, address for exchanging information)	
For University – Principal Investigator Name: Dr. Harold W. (Bill) Kohl Addr: 1616 Guadalupe, Suite 6.300 Austin, Texas 78701 Phone: 512-944-4118 Email: harold.w.kohl@uth.tmc.edu	For City of Austin Healthy Connections Name: Chris Vykukal Addr: 505 Barton Springs Rd. Austin, TX 78704 Phone: 512-585-7811 Email: chris.vykukal@austintexas.gov

3. General Terms	
Purpose	The Purpose of this DUA is to provide Recipient with access to a Limited Data Set ("LDS") for use by Recipient as described in Section 5, below, and Section 5 of Terms and Conditions.
Effective Date	March 1, 2021
Agreement Term	From the Effective Date for so long as Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.

4. **Disclosing Party *("Covered Entity")* Information**	
Name of Covered Entity	*Description of Limited Data Set provided by Covered Entity*
City of Austin Wellness Program Coordinator- Chris Vykukal	De-identified clinical dataset from the City of Austin Diabetes Program including: Height, weight, A1c, Total Cholesterol, HDL, LDL, Triglycerides, blood pressure.

5. **Receiving Party *("Recipient")* Information**	
Name of Recipient	*Description of Recipient's Use of the LDS*
Lauren McGill MS, RD, CSSD, LD	Dissertation "Engagement in a Diabetes Management Program & Clinical Biomarkers in Diverse Municipality Workers"

6. This Agreement may be signed in separate counterparts, and facsimile and electronic signatures will be accepted as originals.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Data Use Agreement.

The University of Texas at Austin
College of
Department of Education

By Lauren McGill
Name Lauren McGill
Title MS, RD, CSSD, LD
Date 3/1/2021

[City of Austin Wellness Coordinator

By Chris Vykukal, CHES
Name Chris Vykukal
Title Wellness Coordinator
Date 3/2/2020

Acknowledgement of Principal Investigator:

By: _ _______ Principal Investigator

_2 March 2021___________ Date

Exhibit A
TERMS AND CONDITIONS FOR
DATA USE AGREEMENT

These Terms and Conditions ("Terms and Conditions") are attached to and incorporated into a Data Use Agreement ("DUA"). All Section number references in these Terms and Conditions shall be references to provisions in these Terms and Conditions unless explicitly stated otherwise.

Background

Covered Entity identified in the DUA own rights in such Party's Limited Data Set ("LDS"). Covered Entity considers it desirable to make Party's LDS available to Recipient for pursuing the Purpose identified in the DUA, subject to the terms and conditions hereof.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. Preparation of the LDS. Covered Entity shall prepare and furnish to Recipient a LDS in accord with the HIPAA Regulations or Covered Entity shall retain Recipient as a Researcher (pursuant to an appropriate and separate Agreement) and direct Recipient, as its Researcher, to prepare such LDS.

3. Minimum Necessary Data Fields in the LDS. In preparing the LDS, Covered Entity or Researcher shall include the data fields specified by the parties from time to time, which are the minimum necessary to accomplish the purposes set forth in Section 5 of this Agreement.

4. Responsibilities of Recipient. Recipient agrees any disclosure of LDS is made in the strictest confidence and to:

Use or disclose the LDS only as permitted by this Agreement, as required by law, or otherwise authorized in writing by Covered Entity;

Safeguard the LDS according to commercially reasonable administrative, physical and technical standards (e.g., National Institute of Standards and Technology, Center for Internet Security, Gramm-Leach Bliley Act) to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law, including all reasonable efforts to ensure the protection, confidentiality, and security of any LDS of Covered Entity in its possession, such efforts to be no less than the degree of care employed by Recipient to preserve and safeguard its own confidential information, but in no event less than a reasonable degree of care;

Continually monitor its operations and take any action necessary to assure the LDS is safeguarded in accordance with the terms of this Agreement;

Provide written notice to Covered Entity of any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law, within one (1) business day after discovery of misuse or disclosure. Recipient will promptly provide all information requested by Covered Entity regarding the impermissible use or disclosure;

Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Recipient under this Agreement; and

Not use the information in the LDS to identify or contact the individuals who are data subjects.
Follow the terms of this Agreement *in addition to* any official policies and standards of University, or their functional equivalent. University policies and standards include, but are not limited to, the Information Resources Use and Security Policy[1], the Acceptable Use Policy[2], the Minimum Security Standards for Systems[3], the Minimum Security Standards for Application Development and Administration[4], the Data Classification Standard[5], the Data Encryption Guidelines[6], the Minimum Security Standards for Data Stewardship[7], and Protecting Sensitive Research Data[8]. Any safeguards in this agreement complement University policy and provide specific guidance for research and business practices, but do not preclude Recipient from adhering to University policy.

In addition to any other termination rights set forth in this Agreement and any other rights at law or equity, if Covered Entity reasonably determines that the Recipient has breached any restrictions or obligations set forth in this section 4, Covered Entity may immediately cancel this, and any other, Agreement for item(s) or services(s) involving the LDS without notice or offer to cure.

5. Permitted Uses and Disclosures of the LDS.

a) Recipient may use and/or disclose the LDS for its Research and Public Health activities and the Health Care Operations of the Covered Entity, specifically including conducting a research Study entitled "**"Engagement in a Diabetes Management Program & Clinical Biomarkers in Diverse Municipality Workers".** Recipient may use the LDS only in accordance with the purposes and procedures set forth in the Study protocol.

b) At the request of the Covered Entity, Recipient agrees to provide Covered entity a written summary of the procedures the Recipient uses to safeguard LDS.

6. Term and Termination.

Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.
Termination by Recipient. Recipient may terminate this agreement at any time by notifying the Covered Entity and returning or destroying the LDS.
Termination by Covered Entity. Covered Entity may terminate this agreement at any time by providing thirty (30) days prior written notice to Recipient.

---

1 http://www.utexas.edu/cio/policies/
2 https://www.utexas.edu/cio/policies/aup/
3 http://www.utexas.edu/its/policies/opsmanual/secstd.php
4 http://www.utexas.edu/its/policies/opsmanual/appstd.php
5 http://www.utexas.edu/its/policies/opsmanual/dataclassification.php
6 http://www.utexas.edu/its/policies/opsmanual/encrypt-guide.php
7 http://www.utexas.edu/its/policies/opsmanual/datastewardstd.php
8 http://www.utexas.edu/its/policies/researchers/

For Breach. Covered Entity shall provide written notice to Recipient within ten (10) days of any determination that Recipient has breached a material term of this Agreement. Covered Entity shall afford Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Covered Entity.
Effect of Termination. Sections 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections (6)c or (6)d.
Disposition of LDS. Upon the first to occur of 1) Termination of this Agreement or 2) completion of the Purpose of this Agreement, Recipient shall return the LDS to Covered Entity and certify destruction of any portion of the LDS not returned.

7. Miscellaneous.
Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.
Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing, or enforcing any of the provisions of this Agreement.
Other Provisions. The Agreement will be governed by the laws of the State of Texas, without regard to choice of law principles. No amendment to the Agreement will be effective unless in writing and signed by the Parties. Neither the Agreement nor the rights and obligations of the Parties hereunder may be sold, assigned or otherwise transferred. If any provision of the Agreement is held to be unenforceable, all other provisions will continue in full force and effect. The Agreement supersedes any and all prior understandings or previous agreements between the Parties, oral or written, relating to the subject matter herein and constitutes the sole and complete agreement between the Parties related to the subject matter hereof. Any delay by a Party to enforce any right under the Agreement shall not act as a waiver of that right, nor as a waiver of the Party's ability to later assert that right relative to any particular factual situation. The Parties acknowledge that nothing in the Agreement shall constitute a

waiver of sovereign immunity by Parties that are state agencies.

[End of Terms and Conditions]

Appendix E: IRB Proposal

The University of Texas at Austin

Office of Research Support & Compliance
Institutional Review Board
P.O. Box 7426, Campus Code A3200
Austin, Texas 78713
T: 512-232-1543 F: 512-471-8873
Email: irb@austin.utexas.edu
www.research.utexas.edu/ors

NOT HUMAN RESEARCH

March 8, 2021

Harold Kohl
2109 SAN JACINTO BLVD
AUSTIN, TX 78712

+1 512 391 2530
hk5689@eid.utexas.edu

Dear Harold Kohl:

On 3/8/2021, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Engagement in a Diabetes Management Program & Clinical Outcomes in Diverse Municipality Workers
Investigator:	Harold Kohl
IRB ID:	STUDY00000793
Funding:	None
Grant Title:	None
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Diabetes Consent form, Category: Consent Form; • Diabetes Flier, Category: Recruitment Materials; • DUA, Category: Other; • McGill_IRB.docx, Category: IRB Protocol;

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations. The activity was determined to be NHSR: PI/PIP confirmed data is de-identified, no interaction with participants; DUA provided.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If you have any additional questions regarding whether future activities

Office of Research Support & Compliance
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www.research.utexas.edu/ors

would be considered human subject research, please contact the Office of Research Support and Compliance at irb@austin.utexas.edu.

Sincerely,

Institutional Review Board

University of Texas at Austin

cc:
Harold Kohl (PI), Lauren Mcgill (Primary Contact)

REFERENCES

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